EXHIBIT 1

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

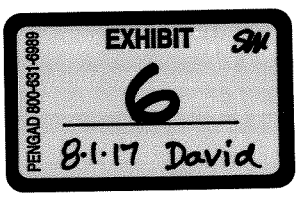
UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 15-2666

Dr. Yadin David Materials: Other Reference Material

1.	ASHRAE Standrad 62-1 2016
2.	Bair Hugger Product Specifications
3.	CDC - HIPAC Meeting Document
4.	FDA QS and GMP Guidelines



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DISTRICT OF MINNESOTA

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Dr. Yadin David Materials: Safer Alternative Design Information

1.	CSZ WarmAir
A.	FilteredFlo® _ Patient Warming Blanket
B.	WarmAir 510k - K123946
C.	WarmAir Family Brochure
D.	WarmAir® Convective Warming _ Patient Warming System
2.	Mistral
A.	Brochure-Mistral-Air-Plus
B.	Mistral Air 510k Summary - K101705
C.	Mistral-Air Plus MA-1100 - Service manual
3.	Tablegard
A.	2011-10-03 3M discusses Berchtold Tablegard - 3MBH01978739
B.	Tablegard 510(k) - K080763
C.	Tablegard Web Advertising - Innovative Surgical Table Surface
D.	Tableguard Brochure
4.	VitaHEAT
A.	VitaHEAT 510k - K132454
B.	VitaHEAT Article-3M Agreement with VitaHEAT...
C.	VitaHEAT Website-The Next Generation in Patient Warming...

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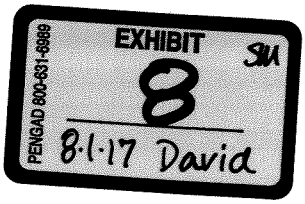
Dr. Yadin David Materials: Literature – Bair Hugger Hazzard

1.	2004-11 - Bernard paper on contamination - 3MBH00018429
2.	2008-10 - Baker Letter on contamination - attachment - 3MBH00002413
3.	2009-10 - Orthopedic Review - Forced Air Warming a Source of Airbone Contam in OR
4.	2009-10 - Standford presentation on contamination - 3MBH00024678
5.	2010-05 - AJIC - Forced Air Warming Blowers An eval of filter adequacy
6.	2011-07 - JBJS - Forced Air Warming and Ultra Clean Ven do not Mix
7.	2011-09 - JBJS - Do FAW devices disrupt unidirect airflow
8.	2011-10 - Anaesthesia - Effect of Force Air Warming on Laminar
9.	2012-04 - A&A - Patient Warming Excess Heat
10.	2012-11 - JBJS - Force Air Blankets Disrupt Unidirec Airflow
11.	2013-08 - AANA Journal - Forced Air Warming Design Eval of Intake Filtration
12.	2013-11 - Jnl of Hosp Infect - Infection Control Hazards Assoc w FAW
13.	2016-06-14 MD Anderson poster on fluid ingress and soot particles - 3MBH01983525

Dr. Yadin David Materials: Literature – Silver ION Treatments

14.	Silver Ion study - Lansdown - 2006 - 3MBH00536470_image
15.	Silver Ion study - Thurman - 1989 - 3MBH00846631_image
16.	Silver Ion study (Feng) - 1999-04-30 - 3MBH00026841_image



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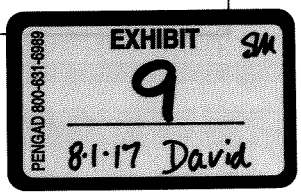
Dr. Yadin David Materials: PDF

1.	1987-09-14 Bair Hugger 510k Notification Letter - 3MBH00047858
2.	1996-01-10 505 510(k) Summary - 3MBH00047382
3.	1999-03-15 Cobra - Zgoda says filter should be same efficiency -3MBH01735994
4.	2000-05-01 Cobra airlow almost double 505 - 3MBH01735812
5.	2000-05-23 Cobra Filtration Meeting - 3MBH00025527
6.	2000-06-01 BH 750 510k safety summary 3MBH00046976
7.	2000-06-01 Letter to FDA from AMI - 3MBH00046971 - EX48
8.	2000-06-07 Cobra filter - using lower efficiency filter - 3MBH00497304
9.	2003-08-26 Westlin - Need letter to file for inferior filter - EX049-001
10.	2003-11-17 Discussion re Bair Hugger 200 not to be used in OR - 3MBH01286161
11.	2006 Call Report - SSI concern on page 2 - 3MBH00135389_image
12.	2006-02-26 Filter test sub 50 percent at 2 microns -3MBH00022367
13.	2006-11-01 Van Duren PR letter re BH bacteria finding - 3MBH00008941_image
14.	2008-07-31 Filtration Topics attachment - 3MBH00022877
15.	2008-08-08 Porous Media says M20 is 58 percent efficent -3MBH00022366_image
16.	2008-10-23 Augustine letter to Westlin - 3MBH00005602_image
17.	2008-12-02 Van Duren on post-MRSA cleaning and filter replacement - 3MBH00024592_image
18.	2009-01-20 Test report approving filter change -3MBH00018311
19.	2009-01-27 No testing on filter over time - 3MBH01807381
20.	2009-03-04 Contamination in BH750 in Texas - 3MBH00024633_image
21.	2009-05-20 Ducky Final Concepts PPT - 3MBH00022625_image
22.	2009-06-15 IonArmour Test Report Copy 3MBH00025006
23.	2009-09-02 Email re Standford presentation - 3MBH00024678
24.	2009-10-02 Scott says BH does not use HEPA due to cost 3MBH00024682
25.	2009-10-15 Van Duren to Westlin - Right to Know EX078
26.	2009-11-30 FDA audit letter 3MBH00048067
27.	2010 - Bair Hugger temp testing - 3M00075103
28.	2010-01-14 Email re new research - 3MBH00002792
29.	2010-01-21 Email re airborne contamination - 3MBH00024733
30.	2010-01-30 Affidavit of Engineers saying BH cannot be cleaned 3MBH00005608
31.	2010-04-02 Augustine letter to Maharaj w attachments - 3MBH00007797_image
32.	2010-06-21 Augustine Letter to 3M 3MBH00023096
33.	2010-09-23 Sessler on Moretti and Huang weaknesses - 3MBH01223897_image
34.	2010-12-08 3M withdraws from upcoming UK study 3MBH00042660
35.	2011-01-02 CRM Report - Fear that NYT article will lead to bio testing - 3MBH00052987_image



36.	2011-02-07 Hansen wants ECRI not to do any tests - 3MBH00544754_image
37.	2011-03-17 Stender to Rock - War games notes - 3MBH00053467
38.	2011-04-29 Discussion of WarmAir and Mistral - EX320-001
39.	2011-09-08 Van Duren Presentation on warming business -3MBH00109049_image
40.	2011-10-03 3M discusses Berchtold Tablegard - 3MBH01978739
41.	2012-03-16 Hansen to Scott - Do not disclose actual filtration level - 3MBH00132832_image
42.	2013-07-30 Need to stop competitor advertisment - 3MBH01254006_image
43.	2013-08-03 Medical director re particulate concern - 3MBH00579800_image
44.	2013-08-24 Hulse-Stevens to counsel re Reed study -3MBH00000826_image
45.	2013-08-24 Van Duren notes on Reed w Hulse Stevens comments - 3MBH01617179_image
46.	2013-10-07 R&D does not want to document filter efficency - 3MBH00126140_image
47.	2014-03-05 Blower Hose Ideation - Tan - 3MBH00630074
48.	2015-05-04 Discussion re not giving customers filter specs - 3MBH02117830_image
49.	2015-07-10 3M Manager to Hulse - high level decision not to pursue research - 3MBH01330587_image
50.	2015-08-20 3M regulatory on reporting requirements - 3MBH01485746_image
51.	UNDATED MedWatch Report - 3MBH00030637_image

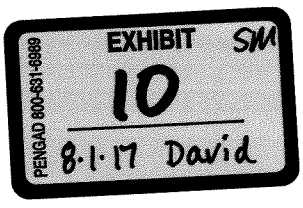
UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 15-2666

Dr. Yadin David Materials

1.	510(k) Bair Hugger Model 505 Warming/Unit/Bair Hugger Blankets
2.	510(k) Bair hugger Model 750 Total Temperature Management System



UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Bair Hugger Forced Air Warming Products Liability Litigation

MDL No. 15-2666

Dr. Yadin David Materials: Depositions

1.	Troy W. Bergstom
2.	Suzanne M. Danielson
3.	Gary L. Hansen
4.	Karl Zgoda (Uncertified Rough Draft Transcript)
5.	John P Rock
6.	Dr. Daniel Sessler
7.	Albert P. Van Duren
8.	David A. Westlin
9.	Teri L. Woodwick-Sides

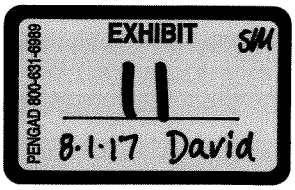


EXHIBIT 2

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation — MDL No. 2666

VIDEOTAPED DEPOSITION OF YADIN DAVID, Ed.D., P.E., C.C.E.

Houston, Texas

Tuesday, August 1, 2017

Reported by:

SUSAN PERRY MILLER, RDR, CRR, CRC

JOB NO. 124787

August 1, 2017

9:16 a.m.

VIDEOTAPED DEPOSITION of YADIN DAVID, Ed.D., P.E., C.C.E., held at the offices of Thompson Coe LLP, One Riverway, Suite 1400, Houston, Texas, pursuant to Subpoena and the Federal Rules of Civil Procedure, before Susan Perry Miller, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Realtime Captioner, and Notary Public in and for the State of Texas.

A P P E A R A N C E S

FOR PLAINTIFFS:

FARRAR & BALL
1010 Lamar Street
Houston, Texas 77002
By: Mark Bankston, Esq.
- and -
KENNEDY HODGES
4409 Montrose Boulevard
Houston, Texas 77006
By: David Hodges, Esq.

FOR DEFENDANTS:

FAEGRE BAKER DANIELS
90 S. Seventh Street
Minneapolis, Minnesota 55402
By: Christin Jaye Eaton, Esq.
- and -
BLACKWELL BURKE
431 South Seventh Street
Minneapolis, Minnesota 55415
By: Peter Goss, Esq.

VIDEO TECHNICIAN: Robert Birdsall

--oOo--

Q. Thank you for that correction.

A. And --

Q. Before the device was obtained for purposes of your review that is described in your report, had you ever seen a Bair Hugger device before?

A. I did.

Q. Tell me about that.

A. I have been working for almost three decades in hospitals, and I recalled walking different areas of these hospitals, especially in the late '90s, that I've seen the Bair Hugger product used in patient rooms.

Q. Is that a specific memory of the late '90s as opposed to other time frames?

A. Correct.

Q. Did your profession -- okay. So you saw a Bair Hugger device in use in patient rooms.

What hospital or hospitals?

A. It would be difficult for me to pinpoint specific hospitals. I'll give you a list of a few of them that I worked at at the time that we are discussing here, and those

Q. Can you give me an example of some biomedical devices?

A. Absolutely. Biomedical devices used for managing and diagnosing patient condition will be bedside monitors that -- looking at patient vital signs. It will be X-ray machines, lasers in surgery. It will be blood-warming devices and laboratory diagnostic instruments.

Q. Is that a complete list?

A. Oh, my God, no.

Q. Okay. Those were examples?

A. I was responsible for about 25,000 devices, biomedical devices, so we probably can spend the day going through the type of biomedical device on these assets.

Q. Would the Bair Hugger device be within the type of devices that you were responsible for?

A. I do not recall.

Q. You don't recall ever making an evaluation or decision about a Bair Hugger device?

A. Correct.

A. Besides the one that I operated?

Q. I'm sorry, my question may not have been clear. For purposes of your work in this lawsuit and preparing the report that you prepared, did you obtain and review and operate a Bair Hugger device?

A. Correct.

Q. Other than -- how many Bair Hugger devices?

A. One.

Q. Other than that one, before you obtained that one, have you ever operated a Bair Hugger device before?

A. Not that I recall.

Q. Have you ever touched one before, in any way?

A. I cannot ascertain that. That does not ring a bell.

Q. You said you had a memory of having seen them in hospitals. Did you -- what is the -- can you tell me more about that memory? What do you recall?

A. No, I cannot.

Q. You recall having seen them and

that's it?

A. Correct.

Q. Okay. Do you recall having any sense, at the time you saw them, for why they were in an operating room?

A. I mentioned it was patient room. I didn't say operating room.

Q. Oh, I'm sorry. Can you please clarify for me, where did you see one?

A. I don't recall it. I don't believe I was walking the operating room.

Q. What do you mean by "patient room"?

A. An area where a patient is being observed on one of the general floors.

Q. Is this something before or after surgery or not in connection with surgery at all?

A. I have no recollection of that.

Q. Do you have any recollection of the specific hardware -- in other words, what model it would be, how large it was, how it compares to the one that you obtained for use in this case?

A. No.

Q. Is this a specific memory of having seen it one time, or do you believe you saw a Bair Hugger device more than one time?

A. We are talking about something that is about 20 years ago or more, so I cannot differentiate if it's one or two times. Definitely not something that would be frequent.

Q. So with the clarification that you saw it in a patient room, do you recall having any understanding at the time you saw it about why it was in the patient room?

A. No.

Q. Do you recall any discussion, ever, during your work at a hospital, about Bair Hugger devices and their use?

A. No.

Q. And I shouldn't have added those last two words, because I meant it to be a very broad question. Do you recall any conversation during your time working in any hospital about Bair Hugger devices?

A. No.

Q. Were you responsible for making any

evaluation or assessment about disposables that are used with medical technology?

A. Yes, I did.

Q. Did you ever make any evaluation or assessment about blankets used with the Bair Hugger device?

A. I don't believe so.

Q. Did every piece of medical technology that came into an operating room become subject to an evaluation by your department, if it was purchased?

A. My ego says answer that as a positive yes so I can reflect on a very good program. I would say the first time a type of device is acquisitioned, probably it will be evaluated. But if the same device is being purchased years later and again and again, it would not.

Q. Did you start the question -- I'm sorry. Did you start your answer by saying your ego would say yes because it was a good program?

A. Yes.

Q. Okay. Meaning, in your mind, if

Q. You don't recall evaluating a Bair Hugger device -- and I apologize if I already asked you this. Do you recall ever evaluating the blankets?

A. I do not.

Q. Had you ever disassembled a Bair Hugger device before the work you did for this case?

A. No, I did not.

Q. And do you have any memory about the way the Bair Hugger device or devices you recall having seen in the past were being operated?

A. No, I do not.

Q. Why did you choose to examine a previously used Bair Hugger device for your work in this case?

A. Actually, this is a very good question. Because usually if you would like to review the device performance, especially in a clinical setting, you would like to have a new product that is fully capable to deliver all these features.

On the other hand, my goal

Y. DAVID

Do you believe that the operation of the Bair Hugger device you examined resulted in any difference in the inside of the compartment than would have occurred if the device had been operated in a different manner?

MR. BANKSTON: Object to the form. Object to the preamble.

A. I need to very simply clarify the purpose of my examination of the device. I wanted to see how the device is built, how it's put together, where the components physically sit, where is the intake, where is the output, how you connect the blanket to it, and I did not seek to make any performance comparison or derive any clinical outcome of the device use.

BY MS. EATON:

Q. When I asked you why you wanted a used device, you said you preferred one so that you could see its characteristics after use. Now that you describe the purpose here, let me ask a different question.

Would a new device have provided

just as much information to you as the one that you examined?

MR. BANKSTON: Object to the form. Object to the preamble.

A. A new device would have a completely different purpose than what I was seeking. I wanted to see the device structure, how it would sustain its integrity of fitting the components together, how the filter fits into the device, where the air intake is, how close it is to a base that it's sitting on. So this was the particular reason that I wanted such a device.

BY MS. EATON:

Q. Did you know that you had available to you a new device?

MR. BANKSTON: Object to the form. Misstates the record.

A. I don't believe that I asked for a new device.

BY MS. EATON:

Q. Okay. What environment was the device that you obtained used in?

A. I didn't receive that information.

Q. For how long had it been in use?

A. The hour meter on the device indicated, as I had written in my report, over 5,000 hours of use.

Q. Do you know how typical that length of use is?

A. No, I do not know.

Q. Do you know how that length of use may have impacted the condition of the device that you had?

A. The length of use will -- may or may not impact the device, and that's why I wanted to examine a used device, to see how well the filter mounting, for example, supports air flow, and to see can you clean the device, can you reach areas that can harbor bacteria or pathogens, and in general, to became -- to make myself acquainted with the product.

Q. Did you see any issue with the filter mounting on the device that you examined?

A. Not on that unit.

Q. Did you see anything about the

A. Since this is the product that I was asked to opine upon, that's the one I requested.

(David Exhibit 2 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 2 the response to the subpoena that was served in this case. Have you ever seen this?

A. Not in this form.

Q. If you would turn to the middle of this packet, there is an eBay -- a printout of an apparent eBay listing. It looks like this (indicating).

A. Yes.

Q. Did you go onto eBay and look for a device?

MR. BANKSTON: Objection to form.

A. I did not.

MS. EATON: What's your objection to that question?

MR. BANKSTON: Asked and answered.

BY MS. EATON:

Q. Do you know who did?

A. Physically who did it, no. What I

know is that I requested counsel to provide me with exemplars, as we discussed earlier.

Q. What type of criteria, if any, did you request in terms of the device you wanted to see?

A. Very simply, a used device.

Q. Any other criteria you requested?

MR. BANKSTON: Objection to form.

A. No.

BY MS. EATON:

Q. Were you given more than one listing to review?

A. No.

Q. Were you given this listing contained in Exhibit 2 to review before the device was purchased to see if it met your criteria?

A. I don't believe so.

Q. Have you ever heard of Spectrum Surgical Solutions before?

A. No.

Q. In your work in hospitals, were refurbished or used medical technologies ever purchased?

A. It's a relatively small display of a few characters and it comes up with the capital letter F, capital letter C, brackets, with a number; and then I believe four digits.

Q. Did you have any source to interpret what those fault codes meant?

A. In the same manual, it had the codes.

Q. What were the fault code numbers that came up?

A. The three recent ones were code 50. The two prior to that, to make a complete total of five, were code 3 and code 8.

Q. Did you make notes of that somewhere, what the codes were?

A. No.

Q. At the time you originally examined the device, did you make notes?

A. No. My computer was with me and I -- after I read the manual, I opened the device under personal protection equipment and operated it and knew how to get to the code memory and look at that.

You see, the simple fact is that I

was not trying to have a device that simulated clinical utilization. My specific reason is to become familiar with the product integrity. So if I would have a device that I needed to do performance testing, I would set it up in a different environment than I used. I would have a protocol with specific tasks, and I will have a document showing the results. That was not my purpose.

Q. Is that something you have done before, what you've just described, the performance testing?

A. Sure.

Q. Okay. In what role have you done that before?

A. I'm doing that continuously for 40 years, so I've done it as a biomedical engineer, I've done it as a research assistant in anesthesia, a dog lab. I've done that as director of biomedical engineering, and I'm doing it now as a consultant.

Q. Is there one set of standards or criteria that you follow when you do that kind of performance testing, or does it vary by

the heater?

A. I am afraid I can't recall.

Q. Was your only source of information about what the code meant this operator manual that you were looking at on the internet?

A. Yes.

Q. Did you do any other research to determine whether that fault code might impact the heating performance?

A. I don't see a need for. I did not seek clinical performance of the device as part of my protocol.

Q. Does that mean you did not do any other research to determine whether that fault code would actually impact the heating?

A. In my experience as a biomedical engineering expert, I understand or I understood at the time the code to mean that there is a problem with the heater, and since I did not set my objective to determine the performance of the device, I did not do any additional investigation on the code.

Q. Did you tell me that -- and I apologize, I'm just not sure if I'm recalling

stretched in the presence of vapors.

Q. Okay. Are you able to give me any quantification at all of the difference at any height with -- either what the difference in height was, what the difference in temp- -- or humidity was, I'm sorry?

MR. BANKSTON: Objection, form.

A. I think we are marching towards an area of guessing. No, I cannot tell you. I can tell you simply that the device would be on the cart most of the time and sometimes I will take it and place it down on the floor just for my education.

BY MS. EATON:

Q. How high was the cart?

A. How high was the cart? I have no clue.

Q. Do you have any expertise in microbiology?

A. I do not.

Q. Do you think that the humidity of an environment makes a difference in the ability of bacteria to survive?

A. Yes, I do.

A. This was a biomedical laboratory.

Q. Okay. Is this laboratory designed to represent an operating room environment?

A. I'm glad that you're asking this question, because once again, I want to make it clear that I did not attempt to look at the device performance or features. I did not need to simulate the environment where its function. Once again, I wanted to see and acquaint myself with the device operation and integration of different components and the air flow through it.

Q. Was the laboratory designed to represent an operating room condition?

MR. BANKSTON: Object to the form.

A. I'm not that familiar with the lab, and I don't know if it was designed for it or not.

BY MS. EATON:

Q. Do you know if it did reflect operating room conditions?

A. Probably did not.

Q. Do you know anything about the air flow into the laboratory?

A. No.

Q. Do you know what the temperature was in the laboratory when you performed the operation that's depicted on page 14?

A. Yes. I took the room temperature.

Q. What was the room temperature?

A. It was exactly as the air-conditioning scale showed, and it was 74 degrees, I believe.

Q. Fahrenheit?

A. Correct.

Q. Is that the temperature of an operating room during surgery?

A. Probably not.

Q. Did you intend for this exercise depicted on page 14 to represent the conditions during clinical use of a Bair Hugger device during a surgery?

A. I might not be communicating clearly enough, so let me try again. My examination was not for clinical performance, was not intended on determining the features and the performance of the Bair Hugger 750 in a clinical environment or in an operating room

or in any area that patients are cared for.

My examination was specifically for acquainting myself with the product elements, with the physical characteristics of how it is functioning, and with understanding the relationship between air intake, air outtake, how the accessories are connected, and that's the extent of it. So we keep coming back to questions about operating temperatures and the lab that is designed to be operating room, and I want to make it clear that if I'm not communicating that issue, I will try it a different way.

But it is a completely different purpose, and knowing that the device has multiple fault codes associated with it, it would be naïve to even try to do that features determination and clinical performance on such condition of the device. So it's further from my goals and objective as can be.

Q. So if we were to show this photograph, for example, these photographs on page 14 to a lay jury, would it be important for them to have that in mind, all that you

just said?

A. Absolutely.

Q. Did any of the pieces of paper get through the intake?

A. No, they did not. The intake spaces of the levers -- I hope I'm identifying it correctly -- but the black cover over the filter has smaller gaps than the size of the paper and the paper cannot penetrate the plastic container that holds the filter in place.

Q. So if we looked at page 12 of Exhibit 3, is that the grate that you're speaking about?

A. Thank you. Very good. Yes.

Q. Okay. So that grate was in place when -- was in place when the exercise was done that's depicted on page 14?

A. Correct.

Q. And all of the paper was stopped by it?

A. Yes.

Q. Did you ever do any test with a smaller-size particle than a sheet of paper?

Q. Was your purpose in doing the work set out on page 14 to demonstrate that, that the Bair Hugger device could lift things off of the floor?

A. The objective of my examination was to understand how the Bair Hugger is functioning, to familiarize myself with the components and integral -- internal integration of the different components and how the accessories are tied into it, and the understanding of how air is entering, getting heated, controlled, and moved out of the unit towards the blanket. That was my purpose of the examination.

The other question that's relating to clinical performance or heating quantification inside the box or outside the box or lifting a specific object from the floor were not part of my examination and were never part of any attempt on my part to prove something.

Q. So the work that is depicted on page 14, for example, would not, in your mind, scientifically prove that the Bair Hugger

device could lift any particular 10-micron particle off the floor, correct?

A. Correct. It's the concept of how air is flowing into and out and what is being condition internally at the Bair Hugger 750 with these components that I see; the filter, the fan, the heating element, the electronic control, the sensors of the temperature that are put in the hose and how the blanket is connected.

Q. All of those things are why you -- what you were looking at?

A. Correct.

Q. Okay. Was there any active fault code at the time that you turned on the Bair Hugger device?

A. No.

Q. Other than the presence of the historic fault code, did you have any reason to believe that the Bair Hugger device was not performing, at the time you looked at it, in the same way that it was performing at previous times?

A. To answer your question, I need to

know how it was performing at previous time. I have no knowledge how it was performing previous time. It might have been defective and abnormally behaving for quite some time according to the fault codes that have many hours of registration to them prior to me handling it.

But beside the point is that I don't believe that I have any intention of looking at performance.

Q. Okay, yeah, I've heard that and thank you. I just want to --

MR. BANKSTON: I'm going to object to you interrupting his answer. Let him finish his answer. We've done that in every deposition I've been with you, and I've had witnesses go extremely -- let the man finish his answer.

BY MS. EATON:

Q. Could we just -- I do understand the purpose for which you've explained you looked at the device. I just wanted to ask something very specific on page 10 with respect --

looked at the device physical structure. I did not attempt to measure any clinical performance. I put temperature probes because I wanted to understand how the device is operating, not to determine if it is reaching specific clinical warming objective or not. I cannot give you a reliable temperature observation because that was not my aim, and what I saw was 36.0, 36.7, 36.9, variety of 36-point-something that was easy to say that on the average they are 36.

BY MS. EATON:

Q. Are those numbers that you just said, 36.0, 6, 7, 9, are those specific memories or is that just a -- let me stop there.

Do you believe that those were specific readings you got?

A. No.

Q. Did you get any readings that were below 36 degrees?

A. I don't believe so.

Q. And you got some readings that were higher than 36 degrees but you can't be

contained in Exhibit 7 and what we discussed this morning with respect to the HotDog?

A. That would be it.

Q. Okay. Did you actually examine any of the devices that are reflected in Exhibit 7 or the HotDog in connection with your work in this case?

A. No.

Q. Have you ever, in your professional -- have you ever -- I'm sorry, let me start over with a clean question.

Have you ever reviewed any of the devices that are listed on the table of contents for Exhibit 7, ever seen them, examined them?

A. That's why I'm looking at the CSZ because I think that I saw that before.

Q. You might have seen that --

A. Yeah.

Q. -- in a hospital?

A. Yeah.

Q. Did you ever examine it for purposes of seeing how it was operated or --

A. Yeah. This was not in a hospital.

It was in outpatient.

Q. Okay. And what -- did you do anything other than just see it?

A. Right. I was in that environment for a different reason.

Q. Is it fair to say that all you did was simply see it in an outpatient environment?

A. Correct.

Q. Did you make any kind of examination or test of that device?

A. No.

Q. Have you ever evaluated any of the devices listed on the table of contents for Exhibit 7 in the course of your professional work?

A. Besides through the literature that is here, no.

Q. In the course of your work outside of this lawsuit, have you ever evaluated any of those devices for a hospital application?

A. I see. No.

Q. I do not believe that we ever received those materials before today, and I

my e-mails. I don't believe I've received them before today, and I have not had a chance to look through them all.

BY MS. EATON:

Q. So you can close that.

(David Exhibit 8 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 8 a table of contents for literature. Is that literature that you reviewed in connection with your work in this case?

A. Yes.

(David Exhibit 9 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 9 a table of contents for certain documents that I could characterize broadly as company documents. Is it your belief that those would correspond to the listing of materials reviewed in your report?

A. They will correspond to footnotes, yes.

Q. Okay. There's an index that I have

marked as Exhibit 9 that has certain descriptions of the documents. Did you make those descriptions or did someone else make those descriptions?

A. I believe that I have a clerical assistant for doing that.

Q. But who provided the substance of the descriptions?

A. I was given the information and the order where it should be.

Q. Did you dictate the substance of those descriptions on Exhibit 9? Is that what you're saying?

A. I'm saying what I said in -- on the telephone, with a clerk, yes.

Q. Are those all of the 3M or Arizant or Augustine Biomedical documents that you reviewed in connection with your work with this case? I should say I have also a 510(k) binder here, so in addition to that.

A. Okay. Yes.

Q. Were those documents provided to you in a single packet?

A. In a single packet? Provided in

boxes, I guess.

Q. Were the documents listed on Exhibit 9 provided to you all at once, together?

A. I see. No, I don't think so. There are different boxes.

Q. Do you recall over what period of time those documents were provided?

A. I would say probably over a four-month period.

Q. In what years?

A. In the -- late 2016 to early 2017.

Q. Do you know how those documents were selected?

A. Well, they're mostly a response to material that I requested.

Q. What did you request that those would be responsive to?

A. I requested the information about the statement by company officers by plaintiff, management relating to product, product development, to changes to the product, to testing and any field reports that were received.

Q. What kind of field reports are you interested in?

A. In the sales rep conveying information of what they see happening in the field.

Q. Is it your understanding that the binder sitting in front of you contains all documents that would respond to that series of categories you just listed that have been produced in this litigation?

A. I'm not sure that I'm following the question.

Q. Do you believe that you received all documents that have been produced in this litigation that relate to the categories that you just described?

A. I see. I do not know if it's all.

Q. Would you be surprised if all of the design and testing documents for these products are contained in that binder?

A. Are or are not?

Q. Are. Would you be surprised if exhibit -- would it be surprising to you if Exhibit 9 contains all of the testing and

design documents for the Bair Hugger devices?

A. No.

Q. You would expect that to be it?

A. I have no expectation. I wanted the material and reviewed what they provided.

Q. Have you ever been involved in designing a medical device?

A. No.

Q. Have you ever reviewed a design history file?

A. No.

Q. Do you know what a design history file is?

A. Yes.

Q. What is a design history file?

A. It's information collected from the engineering aspect of making a product from beginning to end.

Q. Are there any federal regulations that govern the design of a medical device?

A. Federal regulation design, that regulate the design? No. Federal regulation is looking at general processes, guidelines. There's no requirement, just expectation or

guidelines how to do things.

Q. Do any of the federal regulations that you're aware of relate to how to design a medical device?

A. No.

Q. Are you aware of any industry standard that relates to how to design a medical device?

A. There are many guidelines out there by different groups and professional association, consulting, that create a recommended process, guidelines guiding implementation of ideation or innovation, but those are recommendations and guidelines. There's no mandatory.

Q. Are you familiar with any particular recommendation or guideline for designing a medical device that is a prominent one or often used by medical device manufacturers?

A. Again, for designing, no, I'm not aware. I'm aware of testing, but -- the outcome, but not of design.

Q. And when you're speaking of

testing, are you thinking of, for example, ASTM standards?

A. For example, or AAMI or ANSI.

Q. Would those be related to specific tests and how you conduct specific tests?

A. Correct.

Q. Are you familiar with any industry standard for risk assessment of a medical device?

A. Not as a standard. Again, as a guideline and as a recommendation and acceptable practice, but not mandatory.

Q. And is there any particular guideline or recommendation that you're thinking of when you say that?

A. There are several I pointed out in my report to an organization called MITRE, M-I-T-R-E, and there are others that are provided by the Food and Drug Administration and furthermore by the ANSI organization, A-N-S-I.

Q. The MITRE reference that you provided in your report, is that something that you have worked with before in your

professional capacity outside of litigation?

A. I used it, yes.

Q. It looked to me like that was related to the design of a system. Is that correct?

A. That's correct.

Q. I did not see any discussion in that reference about medical devices, and I just wanted to make sure I didn't miss anything. Is that fair?

A. No, that's correct. The concept there is describing how to identify hazard and do a risk assessment of a system. They are a big conglomerate and then they look at system, and my interest in that was from hospital point of view, looking at disaster preparedness for medical technology.

Q. Have you ever used that MITRE system in advising a hospital about disaster preparedness for medical technology?

A. Correct.

Q. What kind of disaster preparedness are you thinking of? What kind of failures might there be that that would relate to?

A. The disaster planning for healthcare provider is a very important functionality because during any kind of disaster, man-made or natural, the population expected at hospitals will be up and running and able to care for the injured, and nevertheless, hospitals are dependent on systems and subjected to failure themselves.

So this disaster preparedness system is completely targeted; the hospital and electrical grid, telecommunication, a monitoring system of patient, an oxygen line, ventilators. So not one of a kind, but system of equipment functioning. Air conditioning will be one of the systems.

Q. And to the extent that medical devices -- let me ask that differently. Would medical devices even be contemplated within that assessment?

A. Sure.

Q. And to the extent that they would be contemplated, would it relate to how they could continue to function if, for example, the electrical grid goes down?

A. That will be one example.

Q. Is there another example that would relate to how medical devices would function in a disaster?

A. Sure. If you do not have access to supply that the product is using, if an environment as far as air temperature, for example, cannot support the limit of the range of temperature that's designed for this device operation, if it goes outside the limitation, and if you have a situation where gas powering the device has been contaminated.

Q. Have you ever applied ISO standard -- have you ever heard of the International Standards Organization and have any familiarity with its standards?

A. Sure.

Q. Have you ever used or applied ISO Standard 14971?

A. I worked with it. I am not sure that I can tell you that I applied it in a project.

Q. How did you work with it?

A. Well, as part of my experience and

training, I went to seminars. I educated myself as to what the standard's purpose and what the principle of the categories that it addresses, and how one will use it as contrast with other risk assessment programs.

Q. What is ISO 14971? What is it intended -- what is it? What does it apply to?

A. It's basically quality system organization.

Q. I'm sorry. ISO Standard specifically 14971, do you know what that addresses?

A. It's addressed risk management.

Q. For what?

A. For medical devices.

Q. Did you consult that in connection with your work in this case?

A. No, I don't believe so.

Q. You are aware of it?

A. I am.

Q. You're aware that the risk in that standard is evaluated in connection with benefit?

Y. DAVID

A. The classification.

Q. Class 1, 2 or 3?

A. Correct.

Q. Okay. And that when FDA is considering the risk, it is considering whether the magnitude of risk is unreasonable in light of the overall risk-benefit context.

Would you agree with that?

A. I would agree.

(David Exhibit 10 marked.)

BY MS. EATON:

Q. Exhibit 10 is a table of contents to a 510(k) for the model 505 and the model 750. Is that correct?

A. Yes.

Q. Did you review those documents?

A. Yes.

(David Exhibit 11 marked.)

BY MS. EATON:

Q. And Exhibit 11 is a table of contents for depositions of certain individuals. Is that correct?

(Document review by witness.)

--oOo--

Y. DAVID

BY MS. EATON:

Q. First, just is it correct that Exhibit 11 is a table of contents listing certain depositions?

A. Yes.

Q. And then were you wanting -- I'm estimating that perhaps you were wanting to compare that list to the list contained in your report?

A. Correct.

Q. Okay. So Exhibit 3 --

A. I need my glasses.

Q. It lists nine depositions on Exhibit 3. Are there nine there?

A. There are nine, yes.

Q. Okay. I don't see a deposition of Mr. Ulatowski in Exhibit 11 and I didn't see it in the box. Do you believe you have in some form reviewed the deposition of Mr. Ulatowski?

A. I believe it's inserted here.

Q. I don't need you to look for it right now, that's okay. You do believe you've reviewed that deposition, correct?

A. Yes.

Q. And do you believe you have reviewed any other deposition besides Mr. Ulatowski's that we would not find in Exhibit 11 or in Exhibit 3?

A. No. But I believe that I inserted it.

Q. Into one of the tabs?

A. Yes.

Q. Okay. I didn't see any table of contents for any expert reports. Do you believe that you brought with you today the expert reports that you reviewed?

Just to show you, your box is now empty. And also, to be complete, there is a document I pulled from the box. Just it wasn't in a notebook. It's titled "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process At 35 Years."

A. There's only one page of Ulatowski deposition here. I thought that I put it in. I don't know what happened.

Q. So now looking in your notebook, you're seeing one page of the Ulatowski

deposition but you believe you had the whole transcript?

A. Right.

Q. Okay. Any other transcript you believe you had?

A. No.

Q. Any other expert report you believe you had that's -- other than the three listed in Exhibit 3?

A. No.

Q. How did you obtain this document, "Medical Devices and the Public's Health," about the 510(k) clearance process?

A. I've asked counsel to produce a hard copy.

Q. How did you know of this document?

A. Part of my practice is to stay on top of what's happening with the regulatory field and it's one of the things that I would be reading.

Q. Okay. I think you said something about an FDA -- this document -- okay, let me -- I'm sorry, let me take that and ask differently.

Was there any document that was an FDA guidance that you used to inform your opinions about the regulatory history of the Bair Hugger devices?

A. Can you ask me again the question?

Q. Was there any specific FDA guidance document that informed your evaluation of the regulatory history of the Bair Hugger devices?

MR. BANKSTON: Object to the form.

A. I think the overall environment of FDA regulation documents like the 510(k) submission process.

BY MS. EATON:

Q. Have you ever worked within the Office of Device Evaluation for FDA?

A. Worked for the FDA? No. I just serve as a consultant for them.

Q. I do want to get to that in a moment, so let me just ask some specific questions. You've never been an employee of the FDA. Is that correct?

A. That is correct.

Q. You have never worked within the Office of Device Evaluation?

A. That is correct.

Q. Have you ever worked within the Office of Compliance?

A. I did not.

Q. Have you ever taken part in reviewing a 510(k) application for clearance?

A. Yes.

Q. On behalf of the FDA?

A. Yes.

Q. In what context?

A. As a member of the advisory panel.

Q. Okay. When did you do that work?

A. It's a public record when the panel is called to admitting. You can find them online. I don't recall when it was done.

Q. Was it once or more than once?

A. More than once.

Q. How many devices -- you're saying as part of your work on the panel, you've reviewed a 510(k) application?

A. Yes.

Q. Okay. For how many devices?

A. I don't know, four, five.

Q. Do you recall what the devices are?

me to find any of the records that you're referring to. Is it your belief that you participated every time the General Hospital and Personal Use Devices Panel has been called since 1993?

A. No. There are times that I was involved with projects overseas and hospitals in China, Israel, Italy, and I wasn't available for a meeting. There are times that due to work at the Medical Center I could not attend, so, no, I did not attend all the meetings.

Q. Do you have any materials from which you would look and let me know which times you did participate and in what years and for what products?

A. No. This material got lost in a flood that the Medical Center suffered, so I don't have that.

Q. Is there a particular expertise you have that you're aware results in you being chosen or asked to serve on certain panels?

A. Sure.

Q. What is that expertise?

A. Biomedical engineering, trained and practice in the largest medical center in the country so I am bringing the engineering and the clinical exposure and appreciation for processes involve technology in patient care environment. It's a unique combination.

Q. Have you ever been involved in reviewing a question of whether a device was substantially equivalent to a predicate device?

A. During the panel convening that the question would come up, yes.

Q. You have a specific recollection that you've been asked to review that question?

A. I have specific recollection that that was one of the subjects that we're asked to consult upon. I don't have a specific recollection what device was involved.

Q. Do you have a specific recollection of what types of information were consulted or considered in that, in connection with that question?

A. From my angle, what I remember are

questions relating to biomedical engineering in the clinical environment. So if I'm not mistaken, one of the devices was a cleaning and sterilizing equipment for proctoscopes, scopes that are used in the rectum, and how you clean it between uses. And this cleaner has a predicate device that said here is why we are substantially equivalent.

The question was relating to how in the real world, in a clinical environment, this other device is being used.

Q. Any other instance you can recall being asked to evaluate a substantial equivalence question?

A. No.

Q. Have you ever inspected a manufacturer on behalf of FDA?

A. No.

Q. Have you ever had any input into any FDA compliance decision?

A. No.

Q. Have you ever been consulted in any of these panels with respect to whether a device was adulterated or misbranded?

A. No.

Q. What is the definition of an adulterated device?

A. A device that has been put on the market with -- featuring performances other than were reported.

Q. Reported to whom?

A. To the regulatory agency.

Q. How does something become a specification or standard against which the regulatory agency would have the ability to compare to determine if a device is adulterated?

A. By comparing the information submitted in the -- if you will take it as a class 2 device, in the 510(k) documents with the actual device performing in the field.

Q. The device would need to be manufactured to the specification stated to the FDA. Is that correct?

A. Would have to, yes.

Q. What is the definition of misbranding?

A. Misbranding is providing

information that is lacking sufficient assurance of safe application.

Q. From where do you get that definition?

A. Where I get the information, I will go to the Code of Federal Regulation.

Q. And do you know where in the Code of Federal Regulation I will find that definition?

A. I think my report is identifying a specific area. There is too much material here for me to remember by heart.

Q. Have you ever been involved on behalf of a company responding to any statement by FDA that a device was adulterated or misbranded in FDA's view?

A. I have not been involved in a company such as that.

Q. Have you ever in your professional capacity in any way, outside of litigation, applied, interpreted or addressed the words "adulterated" or "misbranded"?

A. Sure.

Q. Tell me about that.

A. Throughout my practice at the Medical Center, I was evaluating medical technologies as we discussed this morning and I would look to see that information provided to me by the manufacturers is the same that the device is presenting and that the claims that are being made for the device performance are the same that I'm measuring.

Q. Okay. In terms of the terms "adulterated" and "misbranded," I meant the application of the statute. Would you be applying a federal statute or regulation in the course of your work?

A. No. I'm not involved in the legal profession.

Q. And do you have any understanding about whether -- let's see. Do you have any understanding that FDA ever communicates to companies a statement that a device is either adulterated or misbranded?

A. The FDA would.

Q. In what context would the FDA do that?

A. If they identify that to be the

Y. DAVID

A. I don't remember.

Q. Do you remember for the brain stimulator?

A. Class 2.

Q. And the vascular catheter is still under evaluation?

A. Correct.

Q. For the vascular catheter, what is the advice you're being asked about to provide?

A. What type of testing and information will be required for submission.

Whenever we can take a break...

Q. Pardon? Sure.

THE VIDEOGRAPHER: We are going off the record at 15:20.

(Recess, 3:20 p.m. to 3:32 p.m.)

THE VIDEOGRAPHER: We are back on the record at 15:32.

BY MS. EATON:

Q. Dr. David, have you ever designed a patient warming device?

A. No.

Q. Have you ever made or published any

presentation on Bair Hugger devices?

A. No.

Q. Before your work in this case, had you ever read any studies related to Bair Hugger devices?

A. No.

Q. At any time, have you performed testing related to Bair Hugger devices other than what we have discussed today?

A. No.

Q. At any time, have you performed research related to Bair Hugger devices that is not either reflected in your report or in what we have discussed today?

A. No.

Q. Have you undertaken any effort -- sorry, let me ask that differently.

Before your work in this case, had you reviewed any hospital practices with respect to Bair Hugger devices?

A. A specific brand name Bair Hugger, no. But relating to patient warming, yes.

Q. What had you reviewed related to patient warming prior to your work in this

cardiovascular arena.

Q. Have you looked at the classification regulation for patient warming devices?

A. Yes.

Q. Does it include any special controls?

A. No.

Q. Are you familiar with any industry standard that guides the design or manufacture of patient warming devices?

A. Except the good manufacturing practice, no.

Q. Are you aware of any hospital standard that requires filters to be present on specific patient warming devices?

A. No, I'm not aware.

Q. Are you familiar with the ventilation requirements -- I'm sorry, let me ask that differently.

Are you responsible for evaluating or implementing the ventilation requirements for hospital operating rooms?

A. As we discussed this morning, my

involvement -- my involvement in operating room design and function has evolved over the years and especially here in Texas Medical Center. The hospital I worked with, I have a responsibility for equipment planning and it was in the facility design I would be part of the operating room design team and I would be part of the room air exchanges, temperature controls, humidity --

Q. Thank you. I had forgotten that. You did say that this morning.

Would part of your role involve evaluating or selecting filtration for operating room air?

A. No. I would not select the filters.

Q. Do you have any expertise in filters?

A. Expertise? I understand their function and their construction, how they are rated, how they're being measured, so I have working knowledge of filters and filters' functionality.

Q. That working knowledge, was that

developed in connection with this case?

A. I believe that I described several times today that it's been much beyond that. In the areas of operating room design, cardiac catheterization room design, I was involved with probably 50 or 60 of those facilities and equipment planning and discussion about filtration and filters were part of the team discussion.

I did not select filters, as I said before, but that's where my working knowledge comes from.

Q. Have you ever conducted testing of a filter, any kind of testing of a filter?

A. I don't believe that I did.

Q. Have any of your work responsibilities outside of litigation involved filtration on medical devices specifically as opposed to rooms?

A. The examples that come to my mind as we sit here today are involvements that I have with mechanical ventilators and bedside monitors. Those two product categories involve both protection of the device from

penetration of bacteria from the outside as well as protection of the device from developing pathogens in the internal cavities.

Q. In what context have you worked with those two devices?

A. With the ventilators, I was invited to travel to Travemünde in Germany. That's where Dräger Medical is located and doing their research and manufacturing, and they were developing a new pediatric ventilator and wanted to have an opinion about how the clinicians and the biomedical engineers and the hospital will review their product features.

So they took the medical director of the neonatology ICU, a respiratory therapist director and myself, and we were participating in brainstorming session that looked at how the device is going to be maintained, its cleanliness, in face of some challenging environment, challenging in regard to pathogens.

The other example involved bedside monitoring, and on that product I was invited

to Redmond, Washington, to visit with Space Lab company who developed a new colored monitor for vital signs to be used in intensive care units and wanted to know if the feature of interaction with the display by physically have a touch-sensitive display are appropriate for the environment as to where the monitor will be versus where the operating will be and will -- filter changes will be technically challenged if you have to do so many steps to get to the filters.

Q. For either one of those examples, were you providing any type of microbiology or infectious disease expertise?

A. No.

Q. Have you ever tested filters for efficiency at capturing particles?

A. No.

Q. Has part of your professional responsibility outside of litigation ever involved interpreting filter efficiency testing?

A. I believe that during the project that involved the trace amount of anesthetic

gases in the operating room, we had part of our measurement the air combination level by changing the number of room air exchanges over a certain range in looking for the outcome as well as by changing filters.

Q. Were you providing expertise with respect to the filters and their effect on the air?

A. No. I was part of the team that has -- my part was different role.

Q. Are you familiar with the MERV, M-E-R-V, rating system for filters?

A. Yes.

Q. Are you familiar with that outside of your work on this case? Had you been familiar with that outside of your work on this case?

A. Yes. And MERV is an abbreviation, as you know.

Q. Is that something you used in your work outside of this case or encountered?

A. Encountered. I'm not sure that I'm using it.

Q. Have you seen indication that the

filter for the model 750 Bair Hugger device meets MERV 14 standards?

A. There is test results within the documents that I have here of testing that filter efficiency. But as I sit here, I don't recall by heart what level of MERV that would be.

Q. Do you have any opinion about what the particle capture efficiency of any Bair Hugger filter is separate from a document that you've reviewed in one of the binders sitting in front of you?

A. I don't believe that I understand your question.

Q. Do you have any information about the efficiency of a Bair Hugger filter separate from the documents that are sitting here in front of you?

A. Separate, no.

Q. Have you reviewed any hospital infection rates or records with respect to Bair Hugger use in connection -- I'm sorry, with -- let me ask a better question.

Have you reviewed any hospital

Y. DAVID

A. Can we have a break?

MR. BANKSTON: Yeah, we've been going over an hour and a half.

MS. EATON: Have we?

MR. BANKSTON: Yeah.

MR. GOSS: One hour.

MS. EATON: Okay. It doesn't seem that long to me.

MR. BANKSTON: The room is a little stuffy and we have an older witness. If he wants a break, I'd like to give it.

MS. EATON: That's fine.

THE VIDEOGRAPHER: We're going off the record at 16:33.

(Recess, 4:33 p.m. to 4:54 p.m.)

THE VIDEOGRAPHER: We are back on the record at 16:54.

BY MS. EATON:

Q. Dr. David, do you have any expertise in aerobiology?

A. I don't believe so.

Q. Have you ever tested the effectiveness of any laminar flow system?

A. No, I did not.

Q. Do you have any expertise in air flow or air movement?

A. Expertise, I have a very good working knowledge being in orthopedics operating room, being in the cardiovascular operating room, in general in large concentration of operating room at the Texas Medical Center. I'm talking about 60 to 65 operating rooms and be responsible for all the medical technologies in that area. I fully understand what the unidirectional flow in a protective area is all about. I fully understand design of operating room, of cardiac catheterization laboratory that I was involved with and the placement of objects within that environment.

So I have a very good working knowledge and I can explain to a layperson about it, but I don't believe that I'm expert in that area.

Q. Do you have any expertise in infectious disease?

A. No, I do not.

Q. Do you have any expertise in

surgical site infections?

A. No, I do not.

Q. Do you have any expertise in aseptic technique?

A. Again, I have good working knowledge because this would be part of my involvement in equipment that is present during surgical procedures and in trauma rooms and I will be required to oblige by techniques such as that.

Q. Is our earlier discussion today reflective of your involvement in those matters?

A. It was a specific example. My involvement is much wider because I would be walking literally daily through the operating theater, visiting with the director of the operating room, visiting with surgeons, and looking at the various devices that are being used. So I have intimate interaction with that area.

Q. Do you have responsibility -- I'm sorry, let me ask it differently.

Have you had responsibility within

hospitals for implementing infection control practices?

A. I do not believe that I have the expertise in implementing infection control practices, but as it involves equipment in areas that might have risk of infections and contamination such as intensive care unit and moving ventilators and infusion pumps from one room to another, I have been involved with a team that would implement that type of practice.

Q. Are you a medical doctor?

A. No, I'm not a medical doctor.

Q. Do you have any medical training?

A. I do not have medical training.

Q. Do you have expertise in heat transfer?

A. Being a biomedical engineer, it was one of the courses that I took as part of my academic preparation. Heat transfer is an important physical phenomenon, and I studied and understand it. And I understand the principle operation.

Q. You mentioned radiant heat earlier.

When would -- what percentage reduction in capture of particles at the .2-micron size would result in a filter no longer being substantially equivalent?

A. Excellent question. I would love to see a study that would answer that. We don't have one.

Q. What information would you need to know that you don't know?

A. A clinical study in operating room that do orthopedic surgery with such a filter conducted by infectious disease expert.

Q. Okay.

(Sotto voce discussion.)

BY MS. EATON:

Q. Are you aware of any -- let me say this differently. Are you aware of any clinical data that establishes a different infection risk based on filter characteristics for a Bair Hugger device?

A. I don't believe that as I sit here today I'm prepared to tell you that I'm aware of -- I can search for it, because what I am aware of is that the large amount of

publication are talking specifically about the relationship between filter effectiveness and increased threat of surgical site infection.

And as a matter of fact, we have standards, and in this case I have a policy example from M.D. Anderson, a well-known hospital, that are saying that we have to have filters with HEPA efficiency in those protective environment where the threat of infection in orthopedic surgery is higher than in other locations.

So I'm not here sitting today and can point to here's the study. I can do my homework and find it for you. But I'm saying that the ample data that I am providing here to you today is suggesting that the less efficient the filter is, the higher the threat of infection at the surgical site. There's a simple relationship.

Q. What study, in your mind -- are you able to cite me to a single study, sitting here today, that would establish what you just said?

MR. BANKSTON: Object to the form.

A. In the McGovern study, they have the Bair Hugger and when they removed it and used another patient warming device, there was 81% reduction in infection. With the Bair Hugger, there was 3.8 index increased probability of infection.

At the incident with the literature review that I cited in my report, looking at all the studies, the conclusion was simple that a HEPA filter is one of the ways to mitigate infection. The CDC article that I have in my publication also talks about filtering level efficiency. They -- the literature from orthopedics, Bone & Joint Journal, is talking about one of the solution is increase filter efficiency.

So there's ample evidence out there that there is a relationship between filter efficiency and the potential risk of infection at the surgical site.

BY MS. EATON:

Q. Would a 75% capture of .2-micron particles change the clinical risk as opposed to a 90% capture of .2-micron particles?

A. Counsel, this is an excellent question and I think that the manufacturer of a device who has filters in such environment should do the study and bring the solution, bring the answer. If the solution is there's no difference, use the filter that has only 70%. If the solution is, oh, my God, this is real problem, you better change the filter or change the product. But that's exactly where we are today is that we do not have a properly conducted double-blind study of infection rates in orthopedic surgeries where air-warming -- forced-air warming devices were used and it should be done if a manufacturer is considered to be prudent and care for patient safety.

Q. What size are the bacteria that cause surgical site infections?

A. Look. I have Dr. Hogg's paper here and it has an exact size. You want the viruses that are smaller than 1 microns, you have bacteria between 1 and 6 microns, fungi is above that. We can go back and forth about how much I remember of all this material, but

infection and it did not.

A. I don't think so.

Q. Did you locate any articles that concluded specifically that the Bair Hugger device decreased the risk of surgical site infection?

(Document review by witness.)

A. One of the articles that I indicate and consider is the review article of existing literature by Wood, Moss and Keenan, and I'm not sure, I need to read the study again, but maybe one of the articles there was saying there was no difference. I don't think that there was decrease, but no difference. I just need to read that paper again.

BY MS. EATON:

Q. If there were articles that established that the -- I'm sorry. If there were articles that reported that the use of a forced-air warming device during surgery decreased the risk of surgical site infection, would that be relevant to your consideration?

A. It would.

Q. If there were articles

select only those that had a conclusion that supported your opinion that the Bair Hugger device has the potential to increase infection risk?

A. That's a nice gentle way to suggest that I preselected the articles, but no, I select articles based on the concept of the use of forced warm air device and infection. So those that I have in my report are the articles that they came back.

Q. So if there are articles that would not support an inclusion -- if there are articles that would not support a conclusion that the Bair Hugger device might increase surgical site infection risk, they're not included because you didn't find them?

MR. BANKSTON: Object to the form.

A. I -- I don't know if there are studies of quality and peer-review journal that suggest what you're saying, but if there are, I would like to read them.

BY MS. EATON:

Q. Are you familiar with an article with the first author Kurz, K-U-R-Z?

A. What's the title of the article?

Q. I am not sure by heart. I have it.

THE VIDEOGRAPHER: Christin, I think your mic popped off. It only goes so far.

MS. EATON: Sorry.

THE VIDEOGRAPHER: That's okay.

MS. EATON: Thank you for letting me know.

BY MS. EATON:

Q. "Perioperative Normothermia to Reduce the Incidence of Surgical-Wound Infection and Shorten Hospitalization."

A. The heading doesn't seem like something that would fall within my search.

Q. Does that mean you believe you did or didn't see this article?

A. That probably I did not see it.

Q. Okay. Why would it not fall within your search?

A. Because I provided you the route I took to look specifically at engineering, biomedical engineering type of information relating to infection and this type of patient

warming device. So what you are pointing at probably would not come in my search. Would not come up in my search.

Q. Thank you for that clarification.

Did you make any attempt to assess the clinical benefit that may be provided by normothermia in any respect?

A. I believe that the benefit is discussed in many studies. I don't have to go into these clinical issues.

Q. Do you dispute that the maintenance of normothermia or the prevention of hypothermia results in clinical benefit?

A. For specific patient conditions, I do not.

Q. Is there a surgical -- okay, let me say that differently.

You're familiar that one of the recommended infection control practices for surgery is to maintain normothermia?

MR. BANKSTON: Object to the form.

A. Yes, Counsel, but I believe we talked about cooling down patients during a cardiovascular procedure and bypass of the

heart where specifically you're cooling down patients. I don't believe you want to maintain normothermia in those patients. So I agree with you that certain patient conditions would -- seems to benefit from normothermia, but not all patients.

BY MS. EATON:

Q. Setting aside cardiovascular surgery, any other surgery that you would separate out?

A. I'll have to think about it. I did not prepare myself to respond to that.

Q. Did you make any investigation related to evaluating the potential infection reduction that could result from the use of forced-air warming?

A. I believe you're asking me a clinical question that was not my objective.

Q. Did you make any evaluation of the clinical -- okay, let me say that differently.

What do you mean by that, what you just said?

MR. BANKSTON: Object to the form.

A. What I mean by that is simply that

my charge was to look at the Bair Hugger 750 from hazard and risk control issues, not from clinical outcomes, the type of question you have for me.

BY MS. EATON:

Q. Okay. So making a medical causation determination is not something that you set out to do.

A. Medical causation is not -- what I am prepared to do is to offer the opinion that the Bair Hugger 750, when it is operating in orthopedic surgical procedures, more likely than not will contribute to a higher risk of surgical site infection.

Q. Than what?

A. More likely than not.

Q. As compared to what? I may have misunderstood you.

A. I don't think that I compared it to.

Q. Let me read the answer.

(Counsel reviewing realtime transcript on the reporter's computer.)

--oOo--

Shuttle Challenger disaster happened, I followed clearly -- sorry. I followed intimately the investigation because I wanted to see what they are doing relating to discovery of risk, and one of the team members were talking about more probably than not, this part was subjected to cold temperature below the span of specification.

So yes, it's a nonengineering term.

Q. In terms of making a comparison of the likelihood that one patient warming device would change the infection risk as compared to another patient warming device, have you included in your report everything that you reviewed?

A. Yes.

Q. Is there any clinical data you're aware of that would suggest there's a difference in infection risk between the Bair Hugger device and any other patient warming device that you have identified in your report?

A. I didn't find it, so everything that I did is in my report.

Q. Did you find any studies that suggested the risk was not different between the Bair Hugger device and another type of patient warming device?

A. No, I did not.

Q. Did you look?

A. I believe that I did look and the literature did not have a simultaneously double-blind study with two different products. What they come close to is what I have here, was the McGovern, of removing the Bair Hugger and using something else. And it's clearly -- a clear indication of the improvement in the rate of infection when the Bair Hugger was not there.

Q. Yet you didn't put the HotDog device in your report, right?

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. We can move on because that's already established.

Are you aware of any information about the underlying data from the McGovern study?

A. Underlying data? I've read the article. I understand how it was conducted, how the data was collected. If there's something beyond the study information, no, I don't know.

Q. Have you ever taken any course in epidemiology or biostatistics?

A. I don't think that I have epidemiology courses. I had the courses in engineering about statistics.

Q. Do you consider yourself an expert in biostatistics?

A. No, I'm not.

Q. Okay. Do you consider yourself an expert in epidemiology?

A. No, I'm not.

Q. Okay. Do you have any familiarity with the concept of confounding as it might impact study results?

A. I'm familiar with the concept, yes.

Q. Okay. Did you make any evaluation of the McGovern study and how they did or did not attempt to control for confounding?

A. I read that. I think that the

Q. Are you familiar with what these studies are?

A. Yes.

Q. Okay. Can you briefly explain what the context of these studies are?

A. Yes. I read those articles. Hall is talking about, I believe, eight volunteers that were subjected to a culture count, and Zink is talking about, I believe, 16 patients that were in a completely different environment than orthopedics procedure.

Q. Dr. David, can you tell -- can you tell the jury generally what your impression of your task in this case was?

A. Absolutely. And I actually put it as the first paragraph in my report, that my task was to review the hazards and risk associated with the Bair Hugger 750 family and to opine about if that would contribute to unreasonable dangerous biomedical engineering device that increase the probability of infection in orthopedics procedure or not.

Q. Okay. Can you tell me a little bit -- no, let me take that back. In coming

to an opinion about the -- whether a device more likely than not does or does not pose a patient risk, can you briefly summarize to the jury what you believe qualifies you to render those kind of opinions?

A. That would be an easy task, Counsel. That's something that I have been doing for over 30 years, especially at the Texas Medical Center where I worked 25 years. I was director -- I was the chairman of medical technology evaluation committee with the specific task of reviewing new technology and make recommendation to the hospitals should they acquire and invest in that technology because it will have benefit of lower risk of existing device or increasing patient outcome because of positive feature that they represent.

My committee consists of many representative stakeholders; physicians, nurses, purchasers, administrators, safety officers, risk control and quality control professionals, and facilities engineering, biomedical engineering, and sterile processing

supplies.

So the committee was representing so many expertise and I was in the position where I had to receive their input and derive recommendation to the hospital management if a device is beneficial with lower risk than what is being used today or until that product come.

So I believe that I have the qualification based on academic training and experience working with these stakeholders and with this group to specifically evaluate and assess risk-benefit ratios.

Q. Do you feel like you have enough materials to give yourself an informed and helpful opinion that you can communicate to the jury?

A. I do. And when I felt that I don't have enough material, I approached you, Counsel, and requested specific documents or information. So I'm comfortable that I received the material that I need to arrive at the opinions.

Q. And do you feel confident today

A. No, I did not.

Q. Okay. In performing your work for the hospitals, did you rely on physicians and nurses to provide you with information about clinical risks and benefits?

A. On the clinical side, yes.

Q. Do you understand that it was your responsibility, in preparing your report, to express all of the opinions that you would intend to offer at trial?

A. I do.

Q. And did you also understand that it was your responsibility to provide the bases for those opinions?

A. Yes.

Q. Did you endeavor to do that?

A. Absolutely.

Q. Okay. Are the statements that are contained in your report accurate to the best of your knowledge?

A. They are.

Q. Okay. Is there any prohibition on your discussing published literature with the hospital, to your understanding?

sit here today specific numbers or quantities.

Q. Okay. Are you an expert in -- I'm sorry. Have you made any -- have you made any effort to study, in connection with your work for this case, what are the various risk factors that might impact infection risk in a patient during surgery?

A. When I read the articles, it was obvious that the beginning of the literature talk about the specific basic of infection routes and the sources. So every time I was reading the articles, it addressed that very clearly.

Q. In terms of all the things that might impact patient infection risk from a medical perspective, that's not something you're offering opinions about?

A. I am not.

Q. Have you seen a 500 series filter?

A. I don't know what you mean by "seen." I saw a drawing and I saw pictures in brochures.

Q. Okay. Do you recall what shape it is?

A. It's different than the 750.

Q. Does it differ in size also from the 750?

A. It does.

Q. Have you done any comparison yourself of the filters?

A. There's no need for me to do it. Other expert did that.

Q. Who are you referring to?

A. The literature here in front of us has ample support material for that, so Hanfield is one, three -- letters, letters from defendant officers is another one that --

Q. I'm asking about anything you did, other than review materials.

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. Did you make a comparison of the two filters? Maybe --

A. There is --

Q. You only looked at a drawing of the 500 series filter. Is that correct?

A. Right.

Q. Okay. Do you recall what shape it

was?

MR. BANKSTON: Object to the form.

A. Yeah.

BY MS. EATON:

Q. What shape was it?

A. Square.

Q. Do you recall the -- I'm sorry, what? Do you recall the size of it?

A. I didn't realize I'm in a memory test here. Shape, geometry, size, it's all in the material here. It's all described in detail. It is part of the binders that I have. If you want to take the time, I will go through the material and find it.

Q. I'd rather ask you a question about your report. If you --

MR. BANKSTON: Object to the preamble.

BY MS. EATON:

Q. Do you have any -- actually, what is the basis for your opinion that the Bair Hugger device is adulterated and misbranded? What specific features of it?

A. Very simply, the company misled the

FDA by suggesting that they are a comparable product, that they changed characteristics of major components like the filter, did not communicate that, and yet marketed the device to consumer, confusing and misleading them.

Q. Do you have any basis for an opinion about industry standard other than compliance with FDA regulation?

A. In regard to what?

Q. In regard to the opinions you've expressed in your report.

MR. BANKSTON: I think we're done, Counsel.

MS. EATON: Could we just have an answer to this question?

MR. BANKSTON: Well, you're already past it but I was trying to give you some grace. But you started asking more questions after you've already passed the --

MS. EATON: I don't believe I've asked any question after I was past anything.

Could we have that question read

periprosthetic joint infection."

Q. Okay. So that is something you reviewed in this case?

MS. EATON: Objection to the form.

A. If it's listed here as document, yes.

BY MR. BANKSTON:

Q. The depositions that you reviewed in this case, did they have exhibits to them?

A. Yes.

Q. Do you remember in any of the depositions in this case or in more than one or none of them, was ECRI ever discussed in those depositions?

A. Yes.

Q. Now, in your report, you did not specifically list each and every exhibit of every deposition I see. That's correct?

A. Correct.

MS. EATON: Object to the form.

BY MR. BANKSTON:

Q. Okay. When reading the depositions that had exhibits, those exhibits that are discussed in the deposition, those are parts

of the transcripts that you've read?

MS. EATON: Object to the form.

A. Absolutely.

BY MR. BANKSTON:

Q. The exhibits in the depositions that you reviewed, did you consider them important in coming to your opinions?

MS. EATON: Object to the form.

A. Yes.

BY MR. BANKSTON:

Q. The exhibits that are in the depositions, do you consider them as materials that you have reviewed in coming to your opinions in this case?

A. Very much so, yes.

MR. BANKSTON: Okay.

MS. EATON: Object to the form.

MR. BANKSTON: And we get to go home, Dr. David.

MS. EATON: No, sir. I have a few follow-up questions because what I've been provided doesn't include any exhibits at all and so I definitely have some questions.

Y. DAVID

MR. BANKSTON: You can go to the Court for those.

MS. EATON: I have a few follow-up questions.

MR. BANKSTON: No, you don't. We're going.

MS. EATON: Well, I'm going to ask and you --

MR. BANKSTON: I'm going to tell you what's going to happen. We're going to go because Dr. David needs to go and he has a prior engagement. If you feel like you need to reconvene the deposition, you can attempt to do that through whatever legal avenues you believe are appropriate. But I can tell you what's going to happen right now is at 7:00 p.m., when you began a deposition late and have taken a lot of time preparing in between stuff, we're going to go right now. So that's what's going to happen.

MS. EATON: For the record, the documents that have been provided for me

here today do not include any exhibits at all, and I've received repeated assurances that I have --

MR. BANKSTON: That's strange because my --

MS. EATON: They don't -- they're not contained with the depositions and I've asked if I've received all the materials and I've been told repeatedly yes. So I'd just make a request that we have a search for any additional materials that may have been reviewed because it would appear that there are quite a few that may be missing.

MR. BANKSTON: All right. If you really think that you are hair-splitting enough to say that a person who has read depositions did not also review the exhibits that were discussed in the text of the deposition, I think that's an asinine position. I think providing notice of what depositions were --

MR. GOSS: Let's not get into any name-calling.

C E R T I F I C A T E

STATE OF TEXAS)

COUNTY OF HARRIS)

I, SUSAN PERRY MILLER, CSR, CCR, RDR, CRR, CRC, Notary Public in and for the State of Texas, do hereby certify:

That YADIN DAVID, Ed.D., P.E., C.C.E., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness;

That pursuant to Rule 30 of the Federal Rules of Civil Procedure, signature of the witness was not reserved by the witness or other party before the conclusion of the deposition;

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 11th day of August, 2017.

_____

SUSAN PERRY MILLER, RDR, CRR, CRC

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---------- EXHIBITS ----------

Exhibit 11	Table of Contents for Notebook, "Dr. Yadin David Materials: Depositions"	177	19
Exhibit 12	Augustine Medical Letter, June 1, 2000, to Office of Device Evaluation, FDA; 3MBH00046971 - 46972 [Previously Marked as Exhibit 48]	253	8

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EXHIBIT 3

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re Bair Hugger Forced Air Warming Products Liability Litigation	**MDL No. 15-2666 (JNE/FLN)**

PLAINTIFFS,

v.

3M COMPANY and ARIZANT

HEALTHCARE, INC.

EXPERT REPORT OF TIMOTHY A. ULATOWSKI

FOR DEFENDANTS

TABLE OF CONTENTS

APPENDICES

I. CREDENTIALS AND EXPERIENCE

I have attached my *curriculum vitae*, detailing my education, academic and professional experience, and professional affiliations, as Exhibit A.

I am an expert on matters concerning medical device regulations, policies, and procedures administered by the Food and Drug Administration (FDA or the Agency). I was awarded a Bachelor of Science degree with honors in 1974 with a major in Microbiology from the Pennsylvania State University. In 1987 I was awarded a Master of Science degree in Physiology with an emphasis in Biomedical Engineering from the Georgetown University School of Medicine in a collaborative program with the Catholic University Department of Engineering. I have additional college credits in computer science from the University of Maryland and Charles County Community College.

I was an employee of the FDA from November 1974 until January 2011. During my 36 plus years of employment with the FDA I held positions of increasing responsibility: First for 7 years in what is now known as the Center for Drug Evaluation and Research, and the remaining years in the Center for Devices and Radiological Health (CDRH). CDRH is responsible for evaluation and clearance or approval of new medical devices, evaluation of medical device clinical investigations, ensuring compliance with medical device laws and regulations administered by the FDA, post-market vigilance of marketed devices, and research on emerging device technologies.

From 1974 until 1978 I held the position of Microbiologist in the National Center for Antibiotic Analysis where I conducted laboratory analyses on antibiotics for regulatory certification purposes. From 1978 until 1980 I held the position of Consumer Safety Officer (CSO) in the Office of New Drug Evaluation (ONDE). While at ONDE I was a product manager for the Anti-inflammatory Drugs Group and I also contributed to the Oncology and

Radiopharmaceutical Drugs Groups. I was the Executive Secretary for the Arthritis Advisory Committee and managed the flow of work and outputs concerning investigational new drug applications (INDs) and New Drug Applications (NDAs). I also was the division lead on major issues such as the Drug Efficacy Study Implementation (DESI) program. In my capacity as a CSO I became expert in drug regulations, policies, and procedures.

In 1980 I joined the Office of New Device Evaluation (NDE), Program Management Group, in the Bureau of Medical Devices (BMD) as a CSO. BMD was soon reorganized and joined with the Bureau of Radiological Health to form the Center for Devices and Radiological Health (CDRH). NDE was renamed the Office of Device Evaluation (ODE).

I was assigned to the Investigational Device Staff in ODE and was responsible for formulating policies and procedures to implement the new Investigational Device Exemptions (IDE) regulation, 21 CFR Part 812, and other new human subject protection regulations, 21 CFR Parts 50 and 56, dealing with informed consent and institutional review boards. I evaluated IDE applications, which are submissions to seek permission from FDA to conduct clinical studies of new devices. I provided opinions to industry and FDA staff regarding custom devices, which are defined in the IDE regulation. I also evaluated and quality controlled the IDE review work of all the divisions in ODE.

In 1988 I was promoted to Director of the IDE staff. In that capacity I was responsible for managing and directing the IDE staff, for making final recommendations on the sufficiency of IDE applications and the reviews of those submissions by FDA staff, and for IDE regulatory compliance in collaboration with the Office of Compliance, CDRH. In this position I was the CDRH expert on IDE, IRB and informed consent regulations, policies and procedures.

Later in 1988 I transferred to the position of Branch Chief, General Hospital Devices, in ODE. As Branch Chief I managed and directed the branch staff and was a primary reviewer of IDE applications, Premarket Notification Submissions (510(k)s), Premarket Approval Applications, new product labeling, medical device reports (MDRs) and other types of regulatory submissions under the purview of my branch. My branch evaluated products classified by FDA under 21 CFR Part 880, General Hospital Devices. The products in this classification regulation included, for example, drug infusion devices, administration sets and intravascular catheters. In this position I was an expert in premarket submissions and medical device reporting regulations, policies and procedures. Also, from this appointment forward until the end of my FDA career I was classified by the government as a Supervisory Biomedical Engineer based on my education, training, and experience.

In 1991, I was promoted to the position of Associate Director for General Devices in ODE. The scope of my responsibilities expanded to include the premarket evaluation of surgical devices classified under 21 CFR Part 878 as well as the previously assigned general hospital products. I had broader influence on guidance, policies and procedures spanning the entire ODE. I formulated guidance, policies and actions on many significant new products such as medical lasers and computerized medical systems.

In 1996 I was promoted to the Director, Division of Dental, Infection Control and General Hospital Devices in ODE. In this position I assumed responsibility for more product areas and associated regulatory submissions including devices intended to mitigate the risk of infection (e.g., surgical drapes, gowns, sterilizers, disinfectants, gloves). During my tenure as Director I interacted with government agencies like CDC, NIOSH, EPA, and OSHA and

professional organizations like APIC, AMA, ADA and others on many infection control practice issues.

For over 15 years I participated as a member of various national and international standards committees charged with creating standard specifications for devices, standard test methods to evaluate the performance of devices, and healthcare facility procedures for the users of devices.

I was a representative of the US FDA on the Global Harmonization Task Force (GHTF). The GHTF, which has now transitioned to the International Medical Device Regulators Forum, was tasked with creating globally unified procedures concerning (1) the evaluation of new medical devices, (2) the auditing of manufacturing facilities, (3) the quality system criteria upon which devices are designed and manufactured, (4) the postmarket vigilance of devices, and (5) the clinical assessment of devices. The GHTF consisted of regulators and industry from the European Union, Japan, Canada, Australia and the US. I eventually became the head of the US delegation to the GHTF and a member of the GHTF Steering Committee. In this capacity I interacted with senior level regulators from the GHTF member countries and regulators from many other parts of the globe. During my time on the GHTF I became very familiar with the medical device regulatory procedures used in all the GHTF member countries and in other countries.

I was the co-chair of the FDA committee that created the existing standards program in CDRH. The CDRH standards program evaluates national and international medical device related standards to determine which standards FDA should "recognize" and utilize as means to support device development, manufacturing and premarket submissions. During this time I also

wrote the first FDA guidance documents on infusion pumps and accessories, infusion ports, sterilizers, chemical germicides and labeling of devices intended for reuse.

In 2003 I was promoted to Director, Office of Compliance, CDRH. As the office Director I supervised a large staff that was responsible for ensuring compliance with the medical device, radiological health, and human subject protection laws and regulations administered by FDA. I had many duties, such as the following: determining the work plan for inspections for the forthcoming year and allocating resources for the various aspects of that plan; identifying and prioritizing by risk the manufacturing facilities to be inspected; evaluating and making final agency determinations on actions to be taken based on inspection findings 483s related to the Quality System, correction and removal, bioresearch, and medical device reporting regulations; evaluating various forms of information to identify whether field actions by manufacturers were necessary and communicating with manufacturers regarding those decisions; creating risk management strategies to mitigate emerging public health issues; evaluating manufacturer manufacturing and risk management documents; evaluating advertising, labeling and promotional literature for compliance with labeling and other regulations or statutes; serving as Co-Chair of the FDA Device Field Committee, which is composed of chief inspectors and senior compliance officers; and managing actions related to import/export and registration regulations and statutes. In this position, I was an expert in FDA law and regulations concerning medical devices.

I transitioned to the position of Senior Advisor for Enforcement in October 2010 in anticipation of my retirement and to allow for an orderly succession of leadership. During the last four months of my FDA career, I led a team formulating strategies in advance of user fee

reauthorization, and I provided expert advice to senior FDA leadership on potential changes to premarket and compliance programs.

During my employment with FDA, I received virtually every type of award FDA can bestow including the prestigious Distinguished Career Service Award, Award of Merit, and Commendable Service Award. I received numerous other individual and team member awards as well as yearly performance bonuses. I maintained my management and regulatory expertise during the course of my FDA career by attending numerous professional meetings, courses and seminars. I attended the George Washington School of Law where I studied Food and Drug law. I was frequently the keynote speaker or major participant at regulatory and professional conferences here and abroad such as those held by the Food and Drug Law Institute, Regulatory Affairs Professional Society, and the American Medical Association. I remain current on FDA matters through my memberships with the Regulatory Affairs Professional Society (RAPS) and the FDA Alumni Association, attendance at professional meetings, and surveillance of FDA-related web sites and literature.

I continue to provide training on FDA and international regulation of medical devices to international regulators as an invited speaker at regulatory forums sponsored by the US FDA, the US Department of Commerce, and the US Department of State. According to the Department of Commerce the US FDA has designated me a "trusted speaker" on medical device regulations and procedures.

I currently am an independent consultant and most of my work is contracted through consulting firms such as NSF Health Sciences and NDA Partners LLC. I maintain a registered business in the State of Virginia and the County of Fairfax, Virginia under the name Ulatowski Consulting, LLC.

II. DISCLOSURES

The customary professional fee charged for my consulting time and testimony by NSF Health Sciences in connection with this litigation is $500 per hour. A list of documents I have reviewed and relied upon in the course of my evaluation of the present matter is attached as Exhibit B. I may use all or parts of these materials, or summaries and depictions thereof, as exhibits or demonstrative aids to summarize, support or explain my testimony in this matter. In addition, my opinions are based on my knowledge and experience of FDA regulation of healthcare products, including all applicable laws, regulations, guidance, and policies. I did not rely on any commercial confidential or trade secret information obtained during the course of my employment with FDA in forming my opinions. My previous trial and deposition testimony from the last 5 years is listed in Exhibit C. I have no publications within the past 10 years.

III. BACKGROUND

1. Overview of the Regulation of Medical Devices

FDA regulates medical devices under the authority of the Federal Food, Drug, and Cosmetic Act (the Act). This authority over medical devices was granted to FDA on May 28, 1976, the enactment date of the Medical Device Amendments of 1976. The objective of FDA device regulation is to provide the American public reasonable assurance of safety and effectiveness of all medical devices introduced into interstate commerce.

Title 21 of the Code of Federal Regulations (CFR) codifies the general and permanent rules established by FDA for medical products subject to the Act. Parts 800 to 1299 pertain to medical device requirements including design, manufacturing, marketing authorization, investigational use, classification, post-marketing requirements, and compliance with current Good Manufacturing Practice (cGMP) requirements for finished devices.

FDA periodically issues guidance that represents current thinking by the Agency on a subject. This can take the form of formal guidance documents issued by the Agency, or more informal communication, *e.g.*, teleconferences or face-to-face meetings. FDA guidance does not establish legally enforceable responsibilities, but may cite specific regulatory or statutory requirements.

The basic framework for FDA regulation of medical devices, and the statutory basis for providing "reasonable assurance of safety and effectiveness" of medical devices,[1] rests on a risk-based classification system. Accordingly, FDA has classified all devices into one of three regulatory classes: Class I (general controls), Class II (special controls), or Class III (premarket approval). The class of a device determines the regulatory and statutory controls needed to provide reasonable assurance of safety and effectiveness of that device.

Class I devices tend to be simple devices that present minimal potential for risk and require the least amount of regulation by the Agency. For Class I devices, the general controls of the Act are considered sufficient to provide reasonable assurance of safety and effectiveness.[2] General controls include provisions against adulteration and misbranding, premarket notification[3], good manufacturing practices, establishment registration, and device listing. Examples of Class I devices are stethoscopes, surgical gloves, medical bed linens, hand-held surgical instruments, examination gloves, and elastic bandages.

Class II devices tend to be more complex than Class I devices. They are subject to general controls, but may also be subject to special controls, which together provide reasonable

[1] 21 USC §360c(a).

[2] 21 CFR §860.3(c)(1).

[3] Many Class I and several Class II devices are exempt from premarket notification and portions of the Quality System Regulation.

assurance of safety and effectiveness.[4] Special controls for any given device must be codified by regulation and may include such requirements as conformity to specified standards, specific post-market surveillance obligations, a patient registry, product-specific guidance, and any other actions that FDA determines are necessary to assure reasonable safety and effectiveness. The Bair Hugger Forced Air Warming device is a Class II device.

Class III devices are products that are life supporting or life sustaining or may present a potential for unreasonable risk of illness or injury and general and special controls alone are insufficient to assure safety and effectiveness.[5] Class III devices are subject to general controls and are subject to premarket approval, except for a period of time for certain pre-1976 Class III devices. To market a Class III device subject to premarket approval, FDA requires submission and approval by FDA of a Premarket Approval Application (PMA).

FDA has promulgated regulations under 21 CFR §§860-892 detailing the class of numerous device types grouped by medical systems, e.g., cardiovascular, ophthalmic. When a person intends to market a new device he can compare his new device to the classification listings to identify the type and class for his new device. The class of the device determines the regulatory path to the market.

In general, regulations require that a person notify FDA of his intent to market a potential new Class I or II device at least 90 days before he proposes to introduce the device into commerce. A person notifies FDA by submitting a premarket notification submission, also commonly referred to as a 510(k) submission (aka a "510(k)"). Premarket notification submissions are subject to the requirements of 21 CFR §807, Subpart E - Premarket Notification

[4] 21 CFR §860.3(c)(2).

[5] 21 CFR §860.3(c)(3).

Procedures. Almost all Class I devices are now exempt from the requirement to submit a 510(k) as are some Class II devices.

A 510(k) submission, if required, is the evidentiary basis for FDA to determine the final classification of a new device, i.e., Class I, II, III. Section 510(k) of the Act requires that the person submitting the 510(k) demonstrate from the data and information provided to FDA in the 510(k) that the new device is "substantially equivalent" to a legally marketed Class I or II device, also referred to as a "predicate device."[6] If a person considering marketing a new device cannot identify a legally marketed predicate device then a 510(k) submission is not viable and the device is classified as Class III.[7]

According to the Act and regulations, the term "substantially equivalent" means with respect to the new device being compared to a predicate device that the new device has (1) the same intended use as the predicate device; and (2) it has the same technological characteristics as the predicate device; or (3) has different technological characteristics and the information submitted to demonstrate that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data, if deemed necessary by the FDA, that demonstrates that the device is as safe and effective as a legally marketed device, and does not raise different questions of safety and effectiveness than the predicate device.[8]

[6] A person submitting a 510(k) may rely on more than one predicate device for purposes of establishing substantial equivalence and also include information on specific scientific or engineering aspects of a marketed "reference device" to support the safety and effectiveness of the new device.

[7] There is a statutory process called "de novo" that may be used to classify a low to moderate risk device where there is no predicate into Class II or I. This process is not relevant to knee implants. FDA may assist in identifying an appropriate predicate during the course of a 510(k) review, at a pre-submission meeting, or more formally in response to correspondence.

[8] 21 USC §360c(i)(1)(A) and 21 CFR §807.100(b)(ii)(B).

FDA has interpreted the statutory and regulatory meaning of substantial equivalence and created guidance on the method used by FDA to determine substantial equivalence.[9] According to the guidance, a new device must have the same intended use as the predicate device and technological characteristics to be found equivalent or the different technological characteristics do not raise different questions of safety and effectiveness. FDA will assess the different characteristics based on submitted performance data to determine whether the new device is equivalent.

The three types of 510(k)s are traditional, special, and abbreviated.[10] The traditional 510(k) includes information and test data addressing all the submission requirements listed in the 510(k) regulation. Abbreviated 510(k)s, although also containing information addressing all the submission requirements, include declarations or references to FDA-recognized standards used in the design and/or testing of the device. Special 510(k)s is a submission made by a manufacturer for a change to one of their marketed devices and includes descriptive information and a concise summary of design control activities focused on the specific change.

If FDA finds a new device substantially equivalent to a legally marketed predicate device the new device is classified in the same regulatory class as the predicate, and unless it is a Class III device and a PMA is required, FDA issues an order authorizing its commercial distribution.

A device that was in commercial distribution prior to May 28, 1976, (called a pre-amendments device) that FDA classified as a Class III device, and those new devices found substantially equivalent to this device by means of a 510(k) submission may continue to be

[9] FDA Decision Flowchart, 2014 revised guidance but same flowchart logic, http://www fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

[10] The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications, http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm.

marketed until FDA, by final administrative order,[11] requires the submission and approval of a PMA for these pre-amendments Class III devices.[12]

So, it is the classification and pre-amendments status of a device that dictates the form and manner of submission to FDA, i.e., 510(k) or PMA, for marketing authorization. The manufacturer may not seek to submit a PMA when a 510(k) is viable.

Changes to legally marketed devices subject to premarket notification requirements are subject to strict controls. A new 510(k) for a legally marketed device is required for changes or modifications that could significantly affect the safety or effectiveness of the device.[13] As such, the manufacturer must carefully assess every change or modification to a legally marketed device to determine if it is required to be the subject of a new 510(k) submission.

FDA developed a guidance document to outline the criteria that companies should consider when making decisions to submit – or not to submit – 510(k) notifications for modified Class I, II, or pre-amendments Class III devices not yet subject to premarket approval. In January 1997, FDA issued the guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."[14] This guidance document is still in effect today and has not been modified. It is relied on by industry in making decisions to submit a new 510(k) notification, and by FDA in assessing individual company decision-making in this regard.

The guidance document generally addresses virtually all types of changes that may occur with medical devices, including labeling changes, technology/engineering or performance changes, and materials changes. The document outlines the systematic evaluation process for

[11] Process changed from a final regulation to an administrative order per FDASIA (126 Stat. 156).

[12] Call for PMAs, 21 CFR §860.132. In response to the call for a PMA any person can also submit a petition to reclassify the device from Class III to another class.

[13] 21 CFR §807.81(a)(3).

[14] US Food and Drug Administration, Deciding When to Submit a 510(k) for a Change to an Existing Device (#K97-1), www fda.gov.

companies to use when considering such changes and their regulatory impact, and also provides a framework for the documentation of decisions reached. The guidance document defines common terms, discusses the decision logic that companies should use, presents device-specific examples, and provides a series of flowcharts that clearly outline the thought process to be applied and the outcomes. Companies are expected, although not required, to follow this guidance when determining whether a new 510(k) is necessary for a product change.

Changes to product labeling for Class I and II or pre-amendments Class III devices not yet subject to premarket approval require clearance of a new 510(k) submission by FDA if the intended use is changed or the change is of a type recommended as requiring a new 510(k) in the aforementioned guidance. This also applies to 510(k)-exempt Class I and II devices. Labeling changes to marketed devices intended to enhance safer or more effective use are examples of labeling changes that typically do not require clearance.

Device manufacturers worldwide employ a quality system to help ensure that their finished devices are safe and effective. In the US the current good manufacturing process requirements are set forth in the Quality System (QS) regulation.[15] These requirements govern the methods, facilities and controls used for device design, manufacture, packaging, labeling, storage, installation, and servicing. The regulations specify that each manufacturer shall establish and maintain a Quality System that is appropriate for the specific device(s) designed or manufactured.[16] Certain Class I devices are not subject to all of the QS regulation requirements.

[15] 21 CFR Part 820.

[16] 21 CFR §820.5.

Medical device manufacturers are a diverse group. Many are considered small manufacturers.[17] The QS regulation provides flexibility to companies to establish procedures that work best for their size and for the specific products they manufacture, and their particular intended use. Accordingly, there is no requirement that every company design, manufacture, or market its products in the same manner.

2. FDA maintains broad enforcement authority during the life cycle of a medical device.

The "life cycle" of a device is a term to characterize the period from the point where the product is conceived and the design process begins until the device is no longer on the market.[18] The FDA has in its armamentarium many administrative, advisory, judicial and recall options to enforce the law and regulations during the life cycle of a device, based upon the Act[19] and regulations, as described in FDA regulatory procedures.[20] FDA has seizure, civil money penalty, temporary restraining and injunctive authority. FDA may require a recall of a device. FDA inspects facilities and may issue warning letters based on the inspection,

If at any point during the review of a marketing submission the FDA suspects that the content of the submission, or any other information from a manufacturer, is misleading or fraudulent, it can conduct an unannounced inspection of the submitter's establishment to examine all records FDA deems relevant. If FDA concludes as a result of its inspection that action is required, it may impose safeguards, such as the Application Integrity Policy, which can place the manufacturer's pending premarket submissions in jeopardy.

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[17] FDA has a Division of Small Manufacturers, International and Consumer Assistance to aid small manufacturers in complying with FDA rules and regulations.

[18] FDA has previously coined the term "Total Product Life Cycle" to describe the stages of product marketing and applied regulatory controls. The term "life-cycle" is also used in ISO 13485.

[19] 21 USC §§331-337.

[20] Regulatory Procedures Manual, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProcedures Manual/ucm176446 htm.

3. FDA cleared or approved prescription labeling is the primary regulatory source of information for physicians on the safe and effective use of medical devices.

Labeling for a prescription medical device such as the Bair Hugger must include "indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented."[21] Physicians may also become aware of information concerning a device through training, professional meetings, from other doctors and by other means.

Practitioners licensed by law to have in their possession and to use a prescription device must supervise its use.[22] The regulations do not provide for delegation or transfer of a practitioner's responsibility to be informed regarding the directions for use of a prescription device.

FDA evaluates labeling in marketing applications when it reviews the application. After devices are cleared or approved, manufacturers may not make significant labeling changes without FDA clearance or approval.[23]

4. FDA Review of 510(k) marketing applications is rigorous.

In my opinion there are six important factors in the FDA review of a marketing application, i.e., a 510(k) or PMA, and those are the experience and training of the front line review staff, the contents of the submission, the knowledge base of the review staff on the same

[21] 21 CFR §801.109.

[22] Id.

[23] 21 CFR §807.81(a)(3) and 21 CFR §814.39.

type of product, databases and information sources available to the review, collaboration between review staff, and the supervisory review process.

Based on my 31 years of experience evaluating IDEs, PMAs and 510(k)s I know that the FDA staff is very well trained to review submissions. They come to the FDA with scientific, technical or clinical degrees, many of those advanced degrees, and with advanced experience in engineering, toxicology, medicine and other disciplines.

The FDA review staff are trained how to review the entire contents of a marketing application and to formulate legally sound recommendations based on those reviews. Seasoned FDA experts mentor new FDA reviewers and those experts validate the new reviewer's work until the new reviewer can independently review their assigned portions of submissions. The reviewers utilize guidance and checklists to make sure the submissions are complete and to guide them in their decision-making. Their reviews are documented for the record. FDA conducts frequent training to keep skills at the highest level and those skills are assessed in performance reviews.

The FDA front line reviewers or their mentors have already evaluated prior 510(k)s, IDEs and PMAs for devices that are very similar to the one in the new marketing application under review. For example, the same review team at FDA will be assigned to evaluate an IDE, PMA and 510(k)s for total hip devices. Due to their training, experience, and knowledge of prior submissions, the review staff expect to see specific descriptive information and test data submitted in a marketing application. If information is lacking FDA can request any information it deems necessary to complete its evaluation.

It is the job of the FDA reviewers to thoroughly assess a submission, to uncover areas of significance whether or not those areas are "highlighted" by the submitter, to pose questions on those significant issues, and have them resolved before the review can be completed.

The FDA review is independent and thorough. The FDA drives the review process, not the applicant. While the applicant may seek clarification of FDA's requests or consideration of alternative scientific/clinical/engineering data to respond to FDA's requests ultimately FDA is the final arbiter of what data and information it needs in order to render a final decision.

Databases on adverse effects, recalls, inspections, design and test standards, published literature, and prior submissions, to name a few, are at an FDA reviewer's immediate disposal. FDA reviewers are instructed how to examine these databases and apply their findings in order to identify safety or effectiveness issues that may impact the review of a new marketing application.

No reviewer is isolated from the experience and skills of all other FDA review staff and external advisory committee experts.[24] For any given submission a reviewer may rely on teams of experts within FDA, such as an engineering team within the device Center, to advise him or her on any scientific or medical aspect. Thus, the knowledge base for review of a submission is multiplied by the combined expertise within FDA.

At least two levels of supervisory reviews take place before a final decision on a marketing application is made. The supervisors ensure that the 510(k), PMA or IDE was reviewed according to policy and procedure and that the conclusions are scientifically and

[24] Persons nominated as scientific advisory committee members must be technically qualified experts in their field (e.g., clinical medicine, engineering, biological and physical sciences, and biostatistics) and have experience interpreting complex data. Candidates must be able to analyze detailed scientific data and understand its public health significance. See http://www fda.gov/advisorycommittees/aboutadvisorycommittees/committeemembership/applyingformembership/default htm.

medically sound. The supervisors may seek input from experts in FDA in order to render a decision.

Given these six factors, every marketing submission is thoroughly reviewed in its entirety. In addition to the information in each submission, FDA also has a deep body of information on the type of device under review. FDA staff have a commanding knowledge of this information and they understand the history and scientific/medical context of the type of product being evaluated. All of this knowledge and information is brought to bear by the reviewers when evaluating a submission.

IV. OVERVIEW OF THE BAIR HUGGER TEMPERATURE MANAGEMENT UNIT MODELS 505 AND 750 AND OTHER TEMPERATURE MANAGEMENT SYSTEM SUBMISSIONS TO FDA

The devices associated with this litigation are collectively identified in the Master Long Form Complaint of August 24, 2016, as the "Bair Hugger Forced Air Warming device."[25] Based on the Complaint the model of the Bair Hugger allegedly used on each Plaintiff is not stated. The Complaint refers to the Models 505, 750 and 775. Currently, 3M promotes on its web site only the Bair Hugger Model 775.[26]

Based on the labeling the Models 505, 750 and 775 the Bair Hugger brand Total Temperature Management System consists of a Bair Hugger forced-air temperature management unit and disposable components.[27] These are prescription use only devices.

[25] Complaint, Paragraph 1.

[26] 3M Bair Hugger Warming Units, http://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Bair-Hugger-Warming-Units?N=5002385+3293316253&rt=rud.

[27] 775:http://multimedia.3m.com/mws/media/798454O/model-775-operators-manual-english.pdf, 505: http://multimedia.3m.com/mws/media/798375O/operators-manual-english.pdf, and 750:

The Bair Hugger total temperature management system is intended to treat and prevent hypothermia per the Indications in labeling. In addition, the temperature management system can be used to provide patient thermal comfort when conditions exist that may cause patients to become too warm or too cold. The system can be used with adult or pediatric patients.

The 500 and 700 series devices are designed to operate safely with only 3M Patient Warming components.[28] The 500 and 700 series devices have been designed to operate with only Bair Hugger blankets, Bair Paws gowns and the 241 Body Fluid Warming Set.[29]

The FDA 510(k) submission history of the marketed compatible Bair Hugger blankets and Fluid Warming Set for the Model 505 and 750 are listed in the Model 750 submission to FDA as follows:[30]

[28] See for example, http://multimedia.3m.com/mws/media/824193O/3m-bair-hugger-therapy-accessories.pdf and 3MBH00042837.

[29] 3MBH00042837 and Model 775 labeling, http://multimedia.3m.com/mws/media/798454O/operators-manual-english.pdf; Model 505 labeling, http://multimedia.3m.com/mws/media/798375O/operators-manual-english.pdf; Model 750 labeling, http://multimedia.3m.com/mws/media/798412O/operators-manual-english.pdf; blankets http://multimedia.3m.com/mws/media/768611O/breadth-of-line.pdf; Bair Paws gowns, http://www.3m.com/3M/en_US/company-us/all-3m-products/?N=8707795+5002385+8711017&Ntt=bair+paws&LC=en_US&co=cc&gsaAction=scBR&rt=rs&type=cc; 241 Fluid Warmer, http://www.3m.com/3M/en_US/company-us/all-3m-products/?N=8707795+5002385+8711017&Ntt=241+fluid+warmer&LC=en_US&co=cc&gsaAction=scBR&rt=rs&type=cc.

[30] 3MBH00047012.

Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734)
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.

There are fifteen 510(k) submissions listed on FDA's web site using "Bair Hugger" as a search term.[31] There are four more using "Arizant" as the search term. There is more than one device listed for certain 510(k)s. Line additions to device families can be marketed without

[31]FDA web site listing of 510(k)s for "Bair Hugger", searched 4/19/17, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&Center=&Panel=&ProductCode=&KNumber=&Applicant=&DeviceName=Bair%20Hugger&Type=&ThirdPartyReviewed=&ClinicalTrials=&Decision=&DecisionDateFrom=&DecisionDateTo=04%2F19%2F2017&IVDProducts=&Redact510K=&CombinationProducts=&ZNumber=&PAGENUM=10&SortColumn=dd%5Fdesc.

resubmission to FDA.[32] I also independently confirmed the 510(k) for the Model 110 noted above but not in the FDA search listing below. The FDA web listings are as follows:

510(k) Listing for Bair Hugger devices

Device Name	Applicant	510(K) Number	Decision Date
Modification To:bair Hugger Temperature	Arizant Healthcare Inc.	K053645	03/09/2006
Bair Hugger Temperature Management Syste	Arizant Healthcare Inc.	K041686	06/30/2004
Bair Hugger Temperature Management Syste	Augustine Medical, Inc.	K021473	07/09/2002
Augustine Medical Bair Huuger, Model 750	Augustine Medical, Inc.	K001149	09/06/2000
Bair Hugger Blood/fluid Warmer	Augustine Medical, Inc.	K973741	04/30/1998
Bair Hugger Model 630 Cardiac Blanket	Augustine Medical, Inc.	K964673	06/26/1997
Bair Hugger Model 655 Blanket	Augustine Medical, Inc.	K952864	09/12/1995
Bair Hugger Model 600 Unit, Blankets	Augustine Medical, Inc.	K950416	08/29/1995
Modification Of Bair Hugger Patient Warm	Augustine Medical, Inc.	K933726	01/28/1994
Bair Hugger Torso Blanket - Arms In Mode	Augustine Medical, Inc.	K921165	08/06/1992
Bair Hugger Cub Blanket- Short Model 536	Augustine Medical, Inc.	K920432	06/18/1992
Bair Hugger Patient Warming System	Augustine Medical, Inc.	K920265	03/27/1992
Bair Hugger(r) Patient Warm Syst/baby Wa	Augustine Medical, Inc.	K913734	10/23/1991
Bair Hugger(r) Patient Warming System-mo	Augustine Medical, Inc.	K903360	08/14/1990
Bair Hugger(tm) - Patient Warming System	Augustine Medical, Inc.	K873745	11/06/1987

[32] A new 510(k) is needed for a new device and when the device to be introduced is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use, 21 CFR §807.81(a).

3m Spoton Temperature Monitoring System	Arizant Healthcare Inc.	K120412	05/30/2012
Ranger Rapid Flow Blood/fluid Warming Sy	Arizant Healthcare Inc.	K082217	10/06/2008
Ranger Irrigation Fluid Warming System	Arizant Healthcare Inc.	K060939	06/26/2006
Bair Paws Temperature Management System	Arizant Healthcare Inc.	K060865	04/24/2006
Modification To:bair Hugger Temperature	Arizant Healthcare Inc.	K053645	03/09/2006
Bair Hugger Temperature Management Syste	Arizant Healthcare Inc.	K041686	06/30/2004

Arizant also introduced nonsignificant device model additions by documenting them as a "letter to file." Such additions include, for example, the Models 500OR and 775.[33]

V. SURGICAL SITE INFECTION ALLEGATION IN THE COMPLAINT

The Master Long Form Complaint filed August 24, 2016, alleges in Paragraph 20 "Because of Defendants' actions and inactions, Plaintiffs were injured due to the use of the Bair Hugger, which has caused and will continue to cause bacteria to enter the surgical site, resulting in a dramatic increase in the rate of periprosthetic joint infections among all patient populations. These infections have caused Plaintiffs surgical debridement, premature prosthetic replacement, extended hospital stays, and amputations." In Paragraph 17 the Complaint alleges "At a minimum, Defendants should have warned patients and healthcare providers of the known risk inherent in using the Bair Hugger in orthopedic surgeries."

VI. PURPOSE OF MY REPORT

I was asked to address the allegations concerning regulatory issues in the Master Long Form Complaint and in the report of Yadin David, Ed.D., P.E., C.C.E. entitled "Hazard Analysis Report: Bair Hugger Patient Warming System." I also respond, from a regulatory perspective, to conclusions in the Plaintiffs Memorandum of Law in Support of Motion for Leave to Amend

[33] "Letter-to-file" changes are not described in the 510(k) regulation but are part of the required documentation of design change provisions of the Quality System regulation, 21 CFR 820.30(i). See 3MBH00501669-00501683 for the Model 500OR and 3MBH00501890-00501957 for Model 775 letters to file. Model 500 510(k) submission is K903360.

Master Long Form and Short Form Complaints to Add Claim for Punitive Damages filed April 21, 2017.

VII. METHODOLOGY AND OPINIONS

In forming my opinions, I employed methodologies consistently used by health care companies and regulatory authorities to address and evaluate post-approval safety data, risk reduction strategies and labeling obligations. These methods are also consistent with those utilized by me, the sole member of Ulatowski Consulting, LLC, in the conduct of my assignments with both U.S. and international health care clients manufacturing medical devices including preparation of regulatory submissions and post-market efforts, preparation of regulatory and scientific protocols, labeling and other risk mitigation evaluations. My opinions are also predicated upon the Food, Drug, and Cosmetic Act, my numerous interactions with the Federal Trade Commission on device labeling and promotion, the Code of Federal Regulations, Federal Registers, and industry practices and standards.

My participation in this litigation and the development of the opinions enclosed herein follow an extensive review process. As described earlier, I possess extensive experience in the medical device industry and draw on this experience in conducting my tasks under the auspices of Ulatowski Consulting, LLC, including the reviews provided herein.

As described, I have performed a thorough and integrated review of the publicly available information and regulatory documents, including those produced during discovery, identified in this report and listed in Exhibit B. I analyzed those documents for their relevance. The employed methodology also included a review of the production documents, depositions/transcripts, and other materials provided to me by Counsel, or requested by me from Counsel. Upon retrieval, receipt, and review I considered documents for possible inclusion in the evaluation for this

report. If additional relevant proprietary documentation was required, and I was unable to independently locate this data/information, I made a request of Counsel for any related documents to be reviewed by me. I analyzed these documents for their regulatory relevance and conformity to industry practices and standards in forming my opinions in the same manner I would have assessed them when I was a premarket evaluator or the chief medical device compliance officer at FDA, and also in the same way I would evaluate them in my current capacity as a consultant to companies on medical device regulatory aspects.

The employed methods also include my reviews of depositions, corresponding exhibits, potentially associated with regulatory affairs, post-market surveillance, device design and manufacturing, and medical services, among others. These sources provide me with additional information about the company's action and understanding, which can inform my regulatory assessment.

Based upon my analysis of these documents and information, as well as my experience, knowledge, and training, I have formed opinions with regard to the Arizant/3M Bair Hugger Models 505, 750 and 775. Each of the opinions set forth below is held to a reasonable degree of scientific and regulatory certainty. My prior testimony is listed in Exhibit C. I have no publications in the past 10 years.

I may use visual aids or demonstrative exhibits, such as diagrams, images, slides or charts, to illustrate and or explain my opinions and analyses in this report, as well as excerpts, charts, and other information from the materials I have cited in my report or identified in the materials reviewed.

There are additional materials I expect to review in connection with my work in this case, and I reserve the right to supplement this report and my opinions after that review is completed and as discovery progresses in this litigation.

The name of the company involved in this litigation has changed over time. Originally the company was Augustine Medical, followed by Arizant, and now 3M. My opinions refer to company activities that span a period of time when the name of the company changed. Therefore, for example, I may refer to 3M/Arizant or Augustine Medical/Arizant.

1. It is my opinion that safety and effectiveness factored into FDA's review of every Bair Hugger 510(k).

The undated expert report for Plaintiff by Dr. Yadin David discusses premarket notifications [510(k)s] as well as safety and effectiveness.[34] The 510(k) process is a legitimate premarket process wherein FDA must consider safety and effectiveness aspects identified in statute and regulation to determine whether a new device is substantially equivalent to a legally marketed predicate. FDA did so for every 510(k) for Bair Hugger devices.

In the above background of my report I provide details on FDA's device classification system and the purpose of a 510(k). A 510(k) is used as a basis for FDA to determine whether a new device is substantially equivalent to a legally marketed device. FDA can also bring to bear other information it deems necessary to evaluate a 510(k) in addition to what is submitted in a 510(k).[35] Data submitted in a 510(k) must demonstrate that the new device is "as safe and effective as a legally marketed device."[36]

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[34] Hazard Analysis Report: Bair Hugger Patient Warming System, Yadin David, Ed.D., P.E., C.C.E.

[35] See for example, "FDA relies upon information provided about the predicate device, in addition to the information in our files as appropriate..." in FDA guidance, https://www fda.gov/downloads/MedicalDevices/.../UCM284443.pdf.

[36] 515(i) of the FDCA.

The 510(k) standard is a comparative standard of safety and effectiveness, i.e., comparison of the new device to a legally marketed predicate that is not Class III. The standard for a premarket approval device is an independent determination of safety and effectiveness.[37]

The methodology used by FDA to determine whether any device is substantially equivalent is further described in statute, regulation and guidance.[38] There are several decisions FDA must make when determining substantial equivalence in every 510(k). Three decisions pertain to the intended use of the device, its technology, and performance data.

The new device must have the same intended use as the predicate for the new device to be found equivalent. As noted in FDA guidance FDA must consider issues of safety and effectiveness when comparing any differences in indications for use and claims. When comparing technology FDA makes it clear in guidance that it must consider the effect of differences of technology on safety and effectiveness. When evaluating the submitted performance data, e.g., electrical and mechanical safety, FDA must consider if the data demonstrate equivalent safety and effectiveness.

Additional evidence supports the fact that FDA considers safety and effectiveness factors when evaluating every 510(k). That evidence includes, for example, (1) an FDA Working Group's opinions on 510(k)s (2) the FDA definition of "valid scientific evidence" (3) the FDA definition of "safe" (4) statements in FDA guidance (5) the prohibition on equivalence to unsafe or ineffective devices, and (6) the FDA classification of the device type designated by regulation as "Thermal Regulating System".

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[37] Even though a PMA determination of safety and effectiveness is "independent" the clinical studies used to support safety and effectiveness are always on the basis of comparison to the standard of care, often including legally marketed Class II medical devices used as controls in studies.

[38] Evaluating Substantial Equivalence in Premarket Notifications, https://www fda.gov/downloads/MedicalDevices/.../UCM284443.pdf, 515(i) of the FDCA and 21 CFR Part 807.

FDA Working Group Opinions

In August 2010, an FDA 510(k) Working Group carefully assessed the 510(k) program and provided recommendations to senior FDA management.[39] The report states the following in regard to safety and effectiveness determinations in 510(k)s (emphasis added):

> "With the exception of certain lower risk devices that are exempt from premarket review, CDRH reviews the safety and effectiveness of medical devices for their intended use prior to marketing. Under the premarket approval (PMA) process, each manufacturer must independently demonstrate reasonable assurance of the safety and effectiveness of its device for its intended use. Under the premarket notification (510(k)) process, CDRH will clear a new device if it finds, through review of a 510(k) submission, that the device is substantially equivalent to a predicate. Generally, predicate devices, as largely class II devices, are those for which there is a reasonable assurance of safety and effectiveness with general and applicable special controls."

> "The 510(k) program, as it currently exists,[40] is intended to support FDA's public health mission by meeting two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry."

> "When a predicate has a well established risk/benefit profile and is generally well regarded by the healthcare community, a premarket comparison of a new device

[39] CDRH Internal Preliminary Evaluations – Volume 1, 510(k) Working Group, Preliminary Report and Recommendations, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsand Tobacco/CDRH/CDRHReports/UCM220784.pdf.

[40] The report describes the 510(k) process prior to the assessment by the FDA committee and includes the time when the Bair Hugger device was first evaluated by FDA.

> to that predicate, with sufficient information, can provide reasonable assurance that the device, subject to general and applicable special controls, is safe and effective for its intended use."

In an FDA draft guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications [510(k)] with Different Technological Characteristics" FDA provides ample evidence of its evaluation in a 510(k) of the safety and effectiveness of a device.[41] The guidance states (emphasis added):

> The standard for a determination of substantial equivalence in a 510(k) review is set out in section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)).
>
> Substantial Equivalence
>
> (i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device. . .

[41] Benefit-Risk Factors to Consider When Determining substantial Equivalence, http://www fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm282958 htm.

"Different technological characteristics" is defined in section 513(i)(1)(B) of the FD&C Act (21 U.S.C. § 360c(i)(1)(B)) as: with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device. . .

...if FDA determines that the different technological characteristics do not raise different questions of safety and effectiveness, FDA will then evaluate the technological differences between the new device and the predicate devices to determine their effect on safety and effectiveness. . .

FDA determines the "safety and effectiveness of a device" by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," among other relevant factors. . .

When FDA is reviewing a new device that has different technological characteristics than the predicate device, performance data may be necessary to assess the safety and effectiveness of the new device as compared to the predicate device. When evaluating the performance data, FDA may consider the risks and benefits of the new device in comparison to the predicate device before making a substantial equivalence determination. The type and quantity of performance data that may be necessary to support a determination of substantial equivalence depends upon the new device. Performance data may be generated from both non-clinical and clinical testing, and both non-clinical and clinical data can play a role in FDA's evaluation of benefits and risks. Both types of performance data can provide information relating to the benefit and risk factors discussed in this guidance.

The FDA standard of "Valid Scientific Evidence" applies to both PMAs and the 510(k) Device Classification Process

The determination of safety and effectiveness in a PMA and a finding of substantial equivalence in a 510(k) is based on the statutory and regulatory standard of valid scientific evidence, as stated in regulations as follows:[42]

> "(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.
>
> (2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly

[42] 21 CFR §860.7(c)(1). This provision is also referenced in the FDA guidance concerning benefit-risk, https://www fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm282958 htm .

> and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use."

The 510(k) for the Model 750 included a bibliography of published studies related to burns and the risk of airborne contamination.[43] These papers constitute valid scientific evidence by the regulatory standard noted above.

There is only one definition of "Safe" that applies to all medical devices.

FDA regulations for medical devices contain only one definition of "safe" that applies to all devices. It states as follows:[44]

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

FDA Guidance confirms safety and effectiveness are factors considered in a 510(k).

[43] 3MBH00047033.

[44] 21 CFR §860.7(d)(1).

I refer above to the statutory and regulatory provisions regarding substantial equivalence. There are other examples confirming FDA's evaluation of safety and effectiveness in a 510(k). The Act has been amended several times.[45] One such change was the Medical Device User Fee Act of 2002 (MDUFMA).[46] According to FDA, MDUFMA was enacted "in order to provide the Food and Drug Administration (FDA) with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time…"[47]

A guidance issued by FDA on the determination of substantial equivalence notes the following (emphasis added):[48]

> "Because devices are classified according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness, classification of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues."
>
> ***
>
> "The 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative whereas the PMA standard relies on an independent demonstration of safety and effectiveness.

[45] Amendments to the Federal Food, Drug and Cosmetic Act, http://www.fda.gov/RegulatoryInformation /Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/default htm.

[46] PL 107-250 (Oct. 26, 2002).

[47] MDUFA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109149 htm.

[48] Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], http://www fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review."

FDA cannot find a device to be substantially equivalent to an unsafe or ineffective predicate.

FDA has statutory and administrative tools at its disposal that it uses to eliminate unsafe or ineffective devices from consideration as predicates in a new 510(k). The Act provides, "A device may not be found to be substantially equivalent to a predicate device that has been removed from the market by FDA or that has been determined to be misbranded or adulterated by a judicial order."[49] The Act also provides a mechanism for removing Banned Devices from the market and excluding them as predicates.[50]

FDA may find devices adulterated and/or misbranded as a result of facility inspections or enforcement actions.[51] FDA may ban a device.[52] Recalled devices may be misbranded or adulterated.[53] In the case of devices related to violative facility inspections FDA has broad authority to exercise enforcement discretion when determining whether devices manufactured in the facility may continue to be claimed as predicates.

Thus, there are several means at FDA's disposal to eliminate unsafe or ineffective devices as potential candidates to be used in establishing substantial equivalence. None of the Arizant devices claimed as predicates in Arizant 510(k)s have been determined by FDA to be

[49] 21 USC §360c(i)(2) and 21 CFR §807.100(b)(3).

[50] 21 USC §360f.

[51] http://www fda.gov/ICECI/EnforcementActions/WarningLetters/default htm.

[52] 21 CFR §895.101.

[53] 21 CFR §7.3(g).

unsafe or ineffective. FDA had no basis for action and took none against any of the devices Arizant claimed as predicates in their 510(k)s.

The FDA Cardiovascular Device Classification Panel reviewed data concerning the risks and benefits of existing thermal regulating devices and recommended the group to be Class II.

Expert panels, composed of external clinical and scientific expert consultants, established by FDA classified all devices on the market in 1976 (and those found substantially equivalent to those devices). Those classification panels have transitioned to become the current advisory committees chartered by FDA. These panels rendered safety and effectiveness evaluations of the devices under consideration, creating the initial clinical and scientific basis for future equivalent devices. As regulations provide (emphasis added):[54]

> In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:
> (1) Considers the factors set forth in 860.7 relating to the determination of safety and effectiveness;
> (2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in 860.7;
> (3) Answers the questions in the classification questionnaire applicable to the device being classified;
> (4) Completes a supplemental data sheet for the device;
> (5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.
> (d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device.

FDA reviewed the recommendations of the Cardiovascular Classification Panel and published the final classification regulations on February 5, 1980.[55] The regulations codified the

[54] 21 CFR §860.84(c).

[55] 46 FR 7907-7971, Feb. 5, 1980.

classification of "thermal regulating systems" under 21 CFR §870.5900 into Class II. There are currently no special controls for this type of device. The Class II classifications applied to submissions for subsequent thermal regulating systems, such as the Bair Hugger Models 500 and 750, making them eligible for the 510(k) premarket pathway.

Summation

It is my opinion, based on the above evidence, that safety and effectiveness factors in to the evaluation of equivalence in every 510(k). This was the case for every Bair Hugger 510(k) FDA evaluated.

2. It is my opinion that the Traditional 510(k)s for the Bair Hugger Models 505 and 750 met all FDA premarket requirements, recommendations of guidance, and industry standards. FDA's orders clearing these devices provided, in part, reasonable assurance that the Bair Huggers were safe and effective.

Dr. Yadin's report contains a section entitled "The Bair Hugger's Troubling Regulatory History." Three of the four parts of this section concern the 510(k) process for the Bair Hugger devices. I find there is nothing troubling whatsoever about FDA's clearance of the Bair Hugger devices. As I will explain, contrary to Dr. David's assertion, the 510(k)s for the Models 505 and 750, the principle focus of Dr. David, were submitted in proper form and content, then evaluated and cleared by FDA according to standard FDA policy and procedure.

There is reasonable assurance that a Class II device is safe and effective when it meets all the general controls and any special controls.[56] One general control is the clearance by FDA of a 510(k) for a new device when that submission is required.

[56] 21 USC §360c.

Augustine Medical Inc. submitted a 510(k) to FDA dated April 5, 2000, for the Bair Hugger Model 750 Total Temperature Management System (K001149).[57] I evaluated this 510(k) as I would have during my long tenure as an expert reviewer for FDA and find that the 510(k) conforms to the FDA regulation concerning 510(k) submissions, 21 CFR Part 807 as I explain below.

The administrative and technical data and information addressing the submission requirements are identified in the Model 750 510(k) Table of Contents as follows:[58]

[57] 3MBH00046986-00047093.

[58] 3MBH00046994.

Table of Contents

The submission content and format follow FDA guidance and industry standards.[59] The 510(k) includes all necessary administrative information, technical descriptive information for the Model 750, and technical comparison of the Model 750 to the legally marketed Model 505 Total Temperature Management system (K960167) used by Augustine Medical as the legally marketed predicate for comparative purposes. I find, based on my review and analysis of the original submission and supplemental information submitted to FDA by Augustine Medical, that the submission contains ample and sufficient test data in Section E base on FDA guidance at that point in time. Labeling in Appendix A meets the requirements of the FDA prescription device labeling regulation, 21 CFR §801.109 in that it contains all the required elements identified in the labeling regulation and it is comparable to the predicate labeling.

As I note above in this report, comparable intended use and technology are two essential decision criteria that must be satisfied for a new device to be found substantially equivalent to a legally marketed predicate. There are sufficient data and information in the original submission and the supplemental data submitted to FDA for me to assess and conclude that the Model 750 has the same intended use as the predicate and that the technological characteristics of the Model 750, although not identical to the predicate, do not raise new types of safety and effectiveness issues.

The Bair Hugger system as described in the submission consists of the portable forced air warming unit, a Bair Hugger blanket, and Model 241 fluid warming system if fluid warming is

[59] FDA 510(k) guidance, http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default htm.

desired.[60] I note previously in this report the prior 510(k)s for the Bair Hugger blankets and fluid warmer.[61]

Augustine Medical Inc. reported to FDA in the 510(k) that it relied on voluntary domestic and international test and design standards, and FDA guidance including the following:

EN 60601-1	Electrical safety
EN 60602-2	EMC
ISO 9000	Quality Management
EN 5501	EMC

A Software Requirements Specification (SRS) is documented and approved.

Standards and documents used as references include:

- FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (1998),
- EN 60601-1-4 Medical Electrical Equipment Part 1: General Requirements for Safety Section 1.4 Collateral Standard: General Requirements for Programmable Electrical Medical Systems
- FDA's Guidance for the General Principles of Software Validation – Draft Guidance (1997)
- IEEE Standard 1012-1986; IEEE Standard for Software Verification and Validation Plans
- IEEE Standard 1016-1987; IEEE Standard Practice for Software Design Descriptions

Augustine Medical Inc. amended the 510(k) by letter dated June 1, 2000, to notify FDA it was not marketing the Model 750 with a HEPA filter.[62] Deposition testimony I will discuss later in this report indicates that the Model 750 was not marketed with the HEPA filter but with a filter similar to the predicate. This change did not impede a finding of substantial equivalence since the predicate did not have a HEPA filter.

As noted earlier in this report, FDA requested additional information from Augustine Medical Inc. on July 6, 2000, and Augustine Medical responded to the request. FDA cleared the

[60] 3MBH00047000.

[61] 3MBH00047012.

[62] 3MBH00046971.

Model 750 as a prescription device on September 6, 2000.[63] After clearance, Augustine Medical Inc. informed FDA of modifications to the Model 750 but FDA determined that a new 510(k) was not needed.[64]

I examined the 510(k) litigation production for the Model 505 (K960167), the predicate for the Model 750.[65] This 510(k), like the one for the Model 750, included all the necessary administrative information, substantial technical test data, and adequate labeling according to FDA regulation. The data and information established that the Model 505 had the same intended use as the predicate, there were no new issues of safety and effectiveness, and the data supported the decision that the Model 505 was substantially equivalent.

Both clearance orders from FDA for the Models 505 and 750 provided, in part, reasonable assurance of their safety and effectiveness according to statute.[66] There is nothing troubling in the 510(k) submission records.

3. It is my opinion that after clearance of the Model 750 FDA reconfirmed the safety and effectiveness of the Bair Hugger forced air technology by clearing additional 510(k)s for additional uses and new promotional claims.

As with the FDA clearances for the Models 505 and 750, there is nothing troubling about the other clearances for Bair Hugger modifications and accessories. After FDA cleared the 510(k) for the Model 750 on September 6, 2000, Augustine Medical, then later becoming Arizant Healthcare Inc., submitted additional 510(k)s to FDA for the Bair Hugger. Each time FDA evaluated and cleared a new Arizant Bair Hugger 510(k), the FDA evaluators by policy

[63] 3MBH00046940-00046941.

[64] 3MBH00046932.

[65] 3MBH00047137-00047384.

[66] For example: 3MBH00047159-00047173, 3MBH00047213-00047255.

relied on prior submissions, and other information they can bring to bear according to FDA policy and procedure, such as knowledge of the predicates and their post market performance. FDA was reconfirming the safety and effectiveness of the Bair Hugger technology based on current information with every clearance.

There were several such 510(k)s submitted by Augustine Medical and Arizant after clearance of the Model 750. Augustine Medical submitted a 510(k) (K021473) for modifications to the Models 200, 500 and 700 units with blankets to add the Model 459 patient cooling set.[67] Then FDA evaluated and cleared a Special 510(k) (K041686) to add additional benefit data for the technology.[68] Finally, FDA evaluated and cleared a Special 510(k) (K053645) to add a reduction of anxiety claim based on published data.[69] In all cases the intended use of the devices, except for the cooling function of the Model 459, was localized temperature therapy.

4. It is my opinion that FDA cleared the Model 750 with full knowledge that the air filter to be used in the Model 750 was not a HEPA filter. There is no FDA regulatory requirement for a warming device to meet a specific air filter standard.

On page 20 Dr. David begins a discussion on the filter used in the Model 750. He states that the Model 750 was introduced in 2003. FDA cleared the Model 750 on September 9, 2000. Dr. David asserts "...the Defendant made an unpublished filter change..." for the Model 750 "and never notified the FDA or its customers of this change." He references correspondence dated June 1, 2000 from Augustine Medical to the FDA reviewer of the 510(k) for the Model

[67] http://www.accessdata.fda.gov/cdrh_docs/pdf2/K021473.pdf.

[68] 3MBH00047618-00047723.

[69] 3MBH00047731-00047854.

750. The FDA reviewer was informed of the change in the filter from a HEPA filter to one that Augustine Medical described in the June letter as follows.[70]

> We want to amend the 510(k) to include a filter that is substantially equivalent to the filter currently being used in all of our cleared devices. The description of this filter will be the same, but the physical size will be slightly smaller. With this amendment, the filters in our currently cleared devices (including the SE device Model 505) and the Model 750 will all be 0.2 micron filters.

The revised comparative table attached to the June 2000 letter to FDA describes the filter for the Model 750 as either "0.2 µM or HEPA." The Model 505 filter in the comparative table is described as 0.2 µM. The table also compares such features as Heat generated and Airflow. The revised Summary of Safety and Effectiveness states that "...air is filtered through a filter" instead of "through a HEPA filter." The attached revised Specifications for the Model 750 lists the Filtration System as "0.2 µM or HEPA level (optional)."[71]

It is clear that FDA was informed in the June letter that the Model 750 would include, as an option, a 0.2µm filter as did the Model 505. The publicly available Summary of Safety and Effectiveness lists the correct information regarding the filter. The revised Specifications for the Model 750 include the correct optional filter characteristics. Contrary to Dr. David's assertion, Augustine Medical did not state in the letter that the Model 750 filter had the same efficiency as the filter in the Model 505.

Dr. David discusses the differences in filter media between the Model 505 and Model 750. The filters in each model were both 0.2µm filters but the filter media in each model had different efficiencies at the same 0.3µm level and air flow.[72] This difference is evidently the

[70] 3MBH00049671-00049672.

[71] 3MBH00046975-00046978.

[72] Hansen deposition, 11/2/16, Exhibit 6.

"unpublished information" to which Dr. David refers. He also implies that the findings in the Hall and Zink publications were not applicable to the Model 750.

Augustine Medical stated to FDA that the filters used in both models were "substantially equivalent" 0.2 micron filters. In other words the Model 505 filter media (M10) used until 2009 was substantially equivalent to the Model 750 filter media (M20). Substantial equivalence is a finding by FDA concerning a new finished device and not a component but FDA must consider technological changes in deciding if a new device is substantially equivalent.

FDA guidance on technological changes provides FDA's thinking on this topic. FDA stated in a 1986 Blue Book guidance that it finds devices with technological features to be not equivalent when the new feature (emphasis added) "...could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use."[73] FDA guidance on benefit-risk factors to consider associated with technological change when evaluating 510(k)s must also be considered.[74]

It is my opinion that Augustine Medical's change in filter media from M10 to M20 is not "consequential under the conditions of use." As a result, even recognizing that the media is different the Model 505 and 750 are substantially equivalent. I have four bases for my opinion as follows: (1) There are no publications prior to or after the Model 750 was cleared by FDA that have verified an infection related to any Bair Hugger regardless of filter media. (2) There are no FDA Class II device filter Special Controls for thermal regulating systems, no voluntary standards that stipulate specifications for filters used on thermal regulating systems, nor any

[73] FDA Guidance, K86-3.

[74] FDA Guidance, Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics, https://www fda.gov/RegulatoryInformation/Guidances/ucm282958.htm.

required hospital device filter standards the Bair Hugger must meet.[75] Therefore, there is flexibility in the filter media specifications that can apply to the Bair Hugger filter. (3) The 2016/2017 3M Risk Managements Report for the Bair Hugger, retroactive to the Models 505 and 750, indicates the surgical site risk of infection and assigns the lowest risk level of R1 to the risk.[76] (4) The M10 and M20 filter media have met at least the same Minimum Efficiency reporting Value (MERV) 14 rating that is acceptable for surgery.[77]

Mr. VanDuren testified:[78]

> Well MERV 14 is the -- is -- is in a class of air filters that are specified by ASHRAE as being bacterial exclusion filters and are acceptable for use in healthcare facilities.

***

Mr. Crowder from Pentair (acquired Porous Media) testified as follows:[79]

> **A. Correct.**
> Q. Okay. And have you seen test data establishing a particular MERV rating for that M20 media in the specific filters that Porous/Pentair makes for 3M?
> **A. Yes.**

[75] There are filter standards for operating room air filtration but not for devices in operating rooms.

[76] R1 is described in the 2016/2017 RMR as "Risk is minimum. The potential hazards have either been eliminated or adequately mitigated considering the current state of the art and is supported by an appropriate risk/benefit analysis."

[77] VanDuren depo, Page 22:4-10. See also ANSI/ASHRAE 52.2, https://www.ashrae.org/..

[78] Id. Page 105:9-12.

[79] Crowder deposition, 3/16/17, Page 91:21-92:6 and 54:4-6.

Q. And what MERV rating is that?
A. Fourteen.
Q. Would it be fair to say that a MERV 14 filter is highly efficient at filtering small particles?
A. Yes.

***

A. My understanding is that both of the filter medias or -- that we have supplied would be capable of removing bacteria.

***

Mr. Hansen testified regarding standards as follows:[80]

Then you go on to state "...there is no standard requirement for the convective air warming devices." Do you see that?
A. Yes.
Q. So nobody had a standard out there. The FDA, CDC, National Institutes of Health, no one had a standard; is that right?
A. That's correct.

Next, to assess the benefit/risk of a technological change it is evident that the Model 750 incorporated improvements in design and performance compared to the Model 505 as follows:[81]

[80] Hansen deposition, 11/2/16, Page 169:17-24.

[81] 3MBH00047008.

Summary of Differences

- The Model 750 unit incorporates software as part of the primary temperature control system.
- The Model 750 unit provides greater airflow.
- The Model 750 unit measures the temperature at the distal end of the warming unit hose and displays it on the control panel; the Model 505 unit calculates this temperature. Because of this, the Model 750 unit uses a different warming unit hose.
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to 47 ± 2°C and the secondary over temperature sensor is set to 53 ± 3°C. The primary sensor for the Model 505 unit is set to 53 ± 3°C.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

These improvements, i.e., benefits, should be weighed against any potential increased risks posed by the device with use of the M20 media. FDA risk-benefit guidance states the following:

> *Increased Risk/Increased Benefit*: If the risks associated with the new device increase as compared to the predicate device, FDA may still determine that the new device is SE to the predicate device if, for example, FDA finds from a review of the new device's performance data that there are also increased benefits with the new device as compared to the predicate device.

Therefore, arguendo, although the M20 filter media is less efficient than the M10 media at a 0.3µm particle size (but equally efficient at larger relevant particle sizes according to Hansen), there were increased benefits of the Model 750 compared to the Model 505. As a result, it is my opinion that the Model 750 with the technological change in filter media had an acceptable benefit/risk ratio and was again substantially equivalent.

The argument that the Zink and Hall publication and poster are not applicable to the Model 750 due to the change in media and airflow is incorrect. Although the filter media in the Series 500 devices in Zink publication and maybe the Hall poster was different from the Model 750 the publications demonstrated the fundamental utility of air filtration.[82] This is valid scientific evidence that can be applied to the Model 750. In any case, 3M/Arizant was not required to notify FDA of the change in media.

Dr. David's assertion that the use of the M20 media is "unpublished" implies that the filter media should be listed in labeling for the Model 750 and that FDA should have been told about the change in filter media. The fact of the matter is that FDA found the Model 750 to be substantially equivalent with labeling indicating only the 0.2µm filter characteristic. The original 510(k) did not list the efficiency specifications for the filter media and FDA did not ask for media specifications. Hansen testified regarding notification of customers regarding the change in media as follows:[83]

Q. That's why you didn't want to tell the customers about the nominal; isn't that right?
A. I thought it was misleading.
Q. Because 50 percent of the time they might not catch it and 50 percent of the time they might.
A. No. It was misleading because it wasn't relevant to the much larger particle sizes that are typical for fomites. These types of filters are much more efficient for larger filter sizes -- or excuse me -- larger particle sizes.

In sum, FDA cleared the Model 750 510(k) well aware that the filter was 0.2µm and not a HEPA filter like the predicate. FDA indicated that a HEPA filter could be optional. The filter met a MERV standard that applies to hospital filtration. There is no special control

[82] The Hall poster publication does not actually identify the model of Bair Hugger used in the test so there can be no confirmation of the media.

[83] Hansen deposition, 11/2/16, Page 110:6-15.

requirement for a warming device pertaining to filter specifications. FDA's clearance of the Model 750 established that it was substantially equivalent and therefore reasonably safe and effective for its intended use.

5. It is my opinion that the design history files for the Bair Hugger Models 505 and 750 provide reasonable assurance of the safety and effectiveness of the designs of these devices.

The FDA Quality System (QS) regulation sets forth the current good manufacturing (CGMP) requirements for medical devices.[84] The QS regulation governs the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. According to the QS regulation the requirements are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act.

Manufacturers are required by the QS regulation to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.[85] Design control requirements include provisions for design and development planning, design inputs, design outputs, design reviews, design verification and validation, design transfer to manufacturing, and design changes. According to the QS regulation, the Design History File (DHF) shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.[86] These requirements became effective in 1997 but FDA afforded the industry a grace period for many months afterwards to enable the industry to implement the new requirements. For this

[84] 21 CFR Part 820.

[85] 21 CFR §820.30(a)(1).

[86] 21 CFR §820.30(j).

reason devices designed during this grace period and before may not have records addressing all aspects of the current QS regulation.

I examined the DHFs for the Models 505 and 750 as I did numerous times as chief compliance officer for medical devices at FDA. I relied on the QS regulation, FDA policies and practices, and FDA guidance in my review. I summarize below the contents of DHF for the Model 505, the original design DHF of the Bair Hugger Model 750, and a re-design of the Model 750 DHF.

Table 3 provides a brief summary of the required elements of a DHF and significant examples of the corresponding contents of the Bair Hugger DHFs. Based on my review I found the DHFs contain substantial evidence of the required elements for a compliant DHF.

Summary of Bair Hugger Models 505 and 750 Design History Files

	Model 750	Model 505
	BATES FORMAT 3MBH000XXXXX	BATES FORMAT 3MBH00XXXXXX
DHF Bates	46310-00046818 346819-00046820 46186-46309	127752-129010
FDA DHF Requirements (21 CFR §820.30)	Corresponding DHF Data	
Design and development plans	46729-46730, 46822-46903, 46829, 46200	127758-127796, 127814-127825
Design Input	46312-46313, 46405-46406, 46727, 46188	127754-127755
Design Output	46366, 46416-46439, 46532, 46534, 46562-46573, 46575-46587, 4678-46801	127756-127757, 127987-128131
Design Review	46356-46363, 46381, 46386, 46400, 46440-46441, 46491, 46526, 46547, 46557, 46574, 46598, 46666	12797-27800, 12807-12847
Design Verification	46391, 46404, 46496-46497, 46507-46508,46622 FASCO brochure, 46734, 46282	128132-128365

Design Validation	46668 beta testing, 46306-46307	127848, 12871-12872, 127938-127939
Design Transfer	46668 final design review production run	128745-128859

When reviewing the entire content of the DHFs, as I would as the chief compliance officer at FDA, I found the DHFs not only sufficiently complete but also the following aspects particularly noteworthy:

1. The design inputs are detailed for both the "reduced size" device (aka Model 505) and the "Cobra" file, i.e., the Model 750 Bair Hugger device file.

2. There is ample documentation of design verifications in the DHFs. The DHF information is the source of the information submitted to FDA in the 510(k). The verifications confirm that the design outputs met the requirements of the design inputs.

3. There are numerous required design meetings with various Augustine Medical Inc. staff to evaluate tests and to discuss progress towards completion of the design process and transfer to manufacturing as required. I provide in the above table only a few examples of those meetings.

4. There is risk assessment information, including design and process FMEA, for the 750 redesign, to assess hazards and mitigation of the hazards. There is no record of an FMEA in the Model 505 DHF but this was not essential in a DHF at that point in time.

5. There is responsive information to the design validation requirements of the QS regulation.[87] Notably, there are beta sites consisting of hospitals where the devices were

[87] The QS regulation was published in 1997 but FDA allowed a grace period for industry implementation of design controls including a design history file.

evaluated by medical staff in operating rooms. Ample publications support the performance of the Models 505 and 750.[88]

6. The design inputs for the Model 750 include a requirement for an intake filter (prefilter) that is easy to change and with easy method for cleaning. The Model 505 DHF lists the 0.2µm filter as a design input. Additional records are in the file from the filter supplier.

7. It is remarkable that four years before FDA required design history files and compliance with other aspects of design control Augustine Medical was voluntarily implementing design controls.

In sum, the DHFs contained the data and information on the design process for the Models 505 and 750 that was required after the implementation of design controls in the Quality System regulation.

6. It is my opinion there was no unacceptable risk or regulatory imperative prompting Arizant to modify the Model 750 to include a filter at the distal end of the air supply hose or a silver coating to the interior of the hose.

On page 31 Dr. David begins a section entitled "Defendant's Refusal to Mitigate Patient Risk." He discusses "Project Ducky" and the evaluation of a silver coating on the interior of the hose. There are Bair Hugger design activities described in litigation records and discussed in depositions. Two of them are an activity to consider adding a filter at the distal end of the air supply hose where the blankets connect. The proximal end of the hose is connected to the heater/blower. The other design activity was to consider coating the interior of the air supply hose with an antimicrobial.

[88] Papers in production from 1969 to 2015 regarding normothermia and assessment of infection risks.

The litigation records describe the activity to add the filter as "Project Ducky." Based on deposition testimony this activity was undertaken by Arizant as a response to what industry calls the "Voice of the Customer" design input, rather than a response to an unacceptable risk that required mitigation, such as confirmed surgical site infections caused by the Bair Hugger.

Karl Zgoda, Senior Manager of Product Development at Arizant, described the purpose of the project as follows:[89]

> **A.** I would say that's not correct. It was a project to investigate potential filtration solutions to issue -- to concerns customers may express over filtration. But I would not say it was a goal to add HEPA filter --

Gary Maharaj, CEO of Arizant, also testified regarding the motivation for the additional filter as follows:[90]

> **It was a feasibility assessment, as I recall, to understand because of some customer perceptions about wanting to have an end-of-hose filtration, and so we undertook it to see if we could accomplish that while maintaining the effectiveness of the therapy.**

The other design activity was to assess the addition of a silver coating to the interior of the hose. It is my experience evaluating silver coatings on devices that the coating acts on the surface only. Silver coatings also act only in the presence of moisture, therefore, it would not be effective on moisture-free bacteria in an air flow media. Mr. Hansen testified as follows:[91]

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[89] Karl Zgoda deposition, 2/24/17, Page 86:8-12.

[90] Gary Maharaj deposition, 1/18/17, Page 197:11-16.

[91] Hansen deposition, 11/2/16, Page 265:2-18.

Q. With regard to the hose and the use of antimicrobial material, was that implemented or not?

A. No, it was not.

Q. What were the reasons it was not implemented?

A. We believed that the material was unlikely to be effective.

Q. What was that decision based on?

A. The method of operation for the material required moisture, as I recall, and the hose is a dry environment.

Q. You're saying the application of the antimicrobial material required water?

A. To my understanding, yes.

Q. When it was applied?

A. Well if it's going to release its active ingredient, it needed some moisture to do so.

Arizant's microbiologist stated the following:[92]

I think that it is possible to coat all your suggested surfaces below with the quat antimicrobials and other chemistries. However, I think that realistically speaking you would need reasonable residence time (at least 15 minutes) and humid air to do a decent job of bacterial kill. It may be that you really make a

The testimony provides evidence that Arizant diligently assessed the end-hose filter as a response to customer perceptions, which can be a valid design input. There is no testimony that Arizant's consideration of adding a filter at the distal end of the hose was initiated as a mitigation to an unacceptable risk or a nonconformity requiring a corrective and preventive action as required by regulation.

Arizant determined through testing that the end hose filter had an impact on effective air flow, thus reducing the benefit of the device.[93] Likewise, the company diligently investigated a coating to the interior of the hose but determined the change to be ineffective due to the

[92] 3MBH00542396.

[93] Example, Hansen deposition, Page 282:3-284:6.

properties of silver coatings and the requirements for moisture for effectiveness. Also, Mr. Zgoda testified as follows that the potential supplier of the silver coating could not ramp up to produce the coating as requested:[94]

> "They were a company that had the technology to apply antimicrobial coatings to products, but they didn't really have the ability to -- to do it in production for companies. It was more of a, what I would call a technology or proof-of-concept idea at the time."

Thus, it is my opinion that the company was reasonable and prudent in considering the two design changes and evaluating them according to industry standards. The changes were not adopted for valid scientific reasons. There was no regulatory requirement to pursue these changes or to report these design activities to FDA.

7. It is my opinion the MedWatch reports to FDA in 2016 from Dr. Augustine and his company, all of which were third hand voluntary reports based on Dr. Augustine aided litigation, are biased, incomplete, and unverified. 3M has a reasonable regulatory basis for not reporting litigation-based events to FDA concerning allegations of infections associated with a Bair Hugger.

The Complaint in Paragraph 74 alleges that 3M/Arizant failed to conduct surveillance of the Bair Hugger. One regulatory post market surveillance requirement concerns the submission of medical device reports.

Manufacturers are required by regulation to collect and investigate complaints and submit Medical Device Reports to FDA of reportable deaths, serious injuries and malfunctions. Manufacturers must create procedures, based on the regulations and industry standards and practices associated with those regulations.[95] FDA maintains a public record of MDRs in its

[94] Karl Zgoda, 2/24/17, Page 164:14-18.

[95] 21 CFR Part 803 and 21 §CFR 820.198.

Manufacturer and User Facility Device Experience (MAUDE) database.[96] Reported events in the MAUDE database are either mandatory reports from manufacturers, health care facilities, or importers, or are voluntary reports from health care professionals, consumers or patients.[97]

I searched the FDA MAUDE database for the period 2000 to 2016 for reports related to Bair Hugger devices. I also searched the database for the competing "Hot Dog" device marketed by Augustine Medical Management.[98] The results do not necessarily comprise all the MDRs submitted by these manufacturers if a report was not captured by my search terms.

There are MAUDE reports prior to 2016 for the Bair Hugger. I found 10 MAUDE reports for 2013. A 3M risk management report also notes 10 MAUDE reports.[99] For 2013 the 3M risk management report indicates 8 alleged injury complaints with 1 claim of infection. For 2014 I found 9 MAUDE reports as the 3M report also indicates. For the same period the 3M risk report indicates 29 complaints with 2 claims of infection. For 2015 there are 8 MAUDE reports, and one concerns an infection. The 3M report also indicates 8 MAUDE reports for 2015 and 113 complaints with 103 of those are claims of infection. In 2016 there are 500 MAUDE reports including reference to infections.

According to the following deposition testimony by Dr. Scott D. Augustine he and his company submitted to FDA around 600 MedWatch reports:[100]

> Q. So when you find out about a new lawsuit, somebody on -- in your employ uses you template and fills out an MDR and submits it to the FDA?
> A. Well, we wait 30 days first so that 3M has violated the law on that particular complaint and then we file. But we're way behind right now, so we're more than 30 days out.

[96] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/results.cfm.

[97] MedWatch, https://www.fda.gov/safety/medwatch/.

[98] Search dated 4/21/17.

[99] 3MBH02281401-02281452.

[100] Scott D. Augustine deposition, 3/31/17, Pages 204:22-205:16.

Q. Do you have a rough estimate as to how many you've filed at this point?
A. Probably around 600.
Q. And for any of those 600, have you asked permission of the -- the individual who is identified in the MedWatch MDR to submit an MDR about their situation?
A. No.
Q. In any of those 600 or so, have you communicated with either the hospital or the medical staff involved in the actual treatment of the -- of the patient to see if they were submitting an MDR?
A. No.

I find the delay by Dr. Augustine in reporting the events for a significant period of time after he had concluded that they should be reported so as to impugn the integrity of 3M to be unconscionable. A MedWatch report is intended as a vehicle for reporting serious problems with human medical products and should be timely reported, not delayed for competitive purposes.

The new lawsuits referred to above were catalyzed by activities that Dr. Augustine and his staff characterized as follows:[101]

Plaintiffs' lawyers are already trolling for Bair Hugger product liability cases. See http://www.stlouisinjurylawblog.com/35 and www.surgicalsiteinfectionattorneys.com.

***

Guide
David and Gabe,

Scott and I are preparing a detailed guide to suing 3M/Bair Hugger for orthopedic implant infections. It will contain background, summaries of and links to scientific articles, explanations of the etiology of

[101] Id. Exhibits 16 and 70.

joint infections, a timeline of 3M's knowledge and failure to warn, discovery suggestions...and a half-dozen other useful things.

We intend to offer it to other plaintiffs' firms around the country who express an interest in jumping on this bandwagon. Our staff is preparing a list of the email addresses of AAJ members who do this work, and we may do an email blast. Communications in the AAJ publications may also be a good idea.

My question: Would you like KH to be the author of this Guide? It would help establish KH as the leader in this area. Of course, if KH is the listed author, you guys will want to be comfortable with the content, and I will run everything past you. We are going forward either way, but I want to give you the opportunity if you are interested.

Randy

Dr. Augustine and his company created a draft template for Bair Hugger MedWatch reports that they would populate with some information from the litigation complaints and then file with FDA.[102] I examined a sample of the 2016 Bair Hugger reports on FDA's web site in their native form and a downloaded excel spreadsheet of all the reports and they generally follow the form and content of the draft template.[103] All the reports repeat the same alleged Augustine theory of the connection of the Bair Hugger to surgical site infections.

Dr. Augustine testified he had previously written most of a MedWatch form submitted to FDA by a Dr. Gauthier.[104] The MedWatch form refers to a Baker and King article and to Dr. Suzanne Beavers. The portion of the Baker and King article in the MedWatch report does

[102] Id. Exhibits 32 and 33.

[103] See for example, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi__id=6141608&pc=DWJ.

[104] Id. Exhibit 29 and Page 160:23-161:24.

not identify a Bair Hugger device and actually refers to another device. The MedWatch conclusions pertaining to Dr. Beavers are misstated.[105]

The FDA MAUDE web site discusses the purpose and interpretation of required and voluntary reporters.[106] FDA states on the MAUDE web site that the data in reports may be incomplete, inaccurate, untimely, unverified or biased as follows:

> Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.
>
> - Please note that the MAUDE web search feature is limited to adverse event reports within the past 10 years.
> - MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices.
> - Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report. Establishing a cause-and-effect relationship is especially difficult if circumstances surrounding the event have not been verified or if the device in question has not been directly evaluated.
> - MAUDE data does not represent all known safety information for a reported medical device and should be interpreted in the context of other available information when making device-related or treatment decisions.
> - Variations in trade, product, and company names affect search results. Searches only retrieve records that contain the search term(s) provided by the requester.
> - Submission of a medical device report and the FDA's release of that information is not necessarily an admission that a product, user facility, importer, distributor, manufacturer, or medical personnel caused or contributed to the event.
> - Certain types of report information are protected from public disclosure under the Freedom of Information Act (FOIA). If a report contains trade secret or confidential business information, that text is replaced by "(b)(4)". If a report contains personnel or medical files information, that text is replaced by "(b)(6)". The designations "(b)(4)" and "(b)(6)" refer to the exemptions in the FOIA. For example, "(b)(4)" may be found in place of the product's composition and "(b)(6)" may be found in place of a patient's age.
> - MAUDE is updated monthly and the search page reflects the date of the most recent update. The FDA seeks to include all reports received prior to the update but the inclusion of some reports may be delayed.

The MedWatch reports submitted by Dr. Augustine and his company are third hand at best. They are not voluntarily reported to FDA by the patient or their doctor, nor are they reported to FDA by a law firm.

The MedWatch reports submitted by Dr. Augustine and his company to FDA are incomplete. Many sections of each of the submitted reports are blank or indicated in FDA's

[105] Id. Exhibit 31.

[106] https://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.

MAUDE record as information was not reported to FDA. The alleged causation explanations provided by Dr. Augustine and his company in the MedWatch reports are incomplete root cause analyses and conjecture in that all potential causes of the alleged infections for each patient are not identified and reasons for discounting all of these potential causes except for the Bair Hugger independently for each patient are absent. The alleged causation in all cases is simply based on Dr. Augustine's standard alleged legal theory.

The Event Descriptions in the Dr. Augustine MAUDE reports contain some identifying information of the patient and his/her treatment, allegations of causation based on the Plaintiff's complaint, and litigation based assertions. I consider these Event Descriptions to contain, in part, unverified and biased data. The reports cannot be interpreted or used to reach conclusions about the association, severity, or frequency of problems in any patient.

I believe the alleged circumstances in each of Dr. Augustine's litigation based complaints have not been scientifically or medically verified making it difficult to establish, as FDA states, "the cause-and-effect relationship of each event" in any given patient. The complaints and MedWatch reports are biased because Dr. Augustine and his company catalyzed the complaints and submitted the MedWatch reports. Dr. Augustine is an industry competitor and antagonist to the marketing of forced air warming devices. His deposition testimony confirms he played a role in the pending litigation and formulation of the legal theory upon which the complaints and MedWatch reports were generated.

The Event Descriptions in the MedWatch reports submitted by Dr. Augustine include statements about 3M's failure to report MDRs for the events reported to FDA. The reports allege

Arizant/3M violated regulations due to lack of reporting of the events or timely reporting.

Dr. Augustine testified as follows:[107]

> Well, 3M has a statutory obligation to do it. And once they've been notified by any legal document, and I assume a lawsuit is a legal document, the FDA statute says they've got 30 days to file. And since they haven't filed one of them, we're kind of doing their duty for them, you might say.

There are 20 MDRs for the Hot Dog device for the same time period I examined for the Bair Hugger. The reports for the Hot Dog describe device malfunctions and patient injuries. I believe that were it not for the litigation-based reports generated by Dr. Augustine the number of MAUDE reports for the Bair Hugger and the Hot Dog devices would be similar.

Suzanne M. Danielson, Director of Regulatory Affairs and Quality Compliance for 3M's Healthcare Business Group testified as follows concerning 3M's MDR reporting in general and specifically regarding the litigation based reports for the Bair Hugger:[108]

> We have a process for reviewing every complaint that comes into 3M, including a legal complaint, and that process involves assessing whether or not an injury occurred and then looking at -- we -- we apply the definition in the medical device regulation which states you review -- you review each event in terms of is there information that suggests that the event -- that the device may -- reasonably -- reasonable information to suggest that the device may have caused or contributed to the event.
>
> ***
>
> As I mentioned earlier, in this -- relative to complaints regarding infection, the only complaints that 3M has received has been through law firms related to litigation. So we have not received any facilities that have reported that they have a concern regarding infection in the Bair Hugger.
>
> ***
>
> In this case this is a -- we have a very unique situation here where there is many -- you

[107] Augustine deposition, 3/31/17, Page 205:21-206:2

[108] Suzanne M. Danielson deposition, 3/17/17, Pages 95:24-96:2, Page 100:4-9, Page 103:3-15, Page 119:10-22.

> know, hundreds of legal cases that come in with essentially no information in terms of the specifics; so they talk about the Bair Hugger was used, the patient had infection. That's essentially the information that comes in. So each of those cases are reviewed, and the -- and in this context we have to -- we -- we have reviewed it in a very holistic way because the -- the complaints are questioning the design of the device. So we have reviewed it very holistically, we have utilized qualified persons, as defined, to evaluate the situation.
>
> ***
>
> But I think in order to be completely responsive it would be important to share that the -- 3M has corresponded to the agency specifically relating to -- well over a year ago, relating to our MDR process, our MDR filing determinations so that the agency has a, I think a very good understanding of the situation, what's been reported, and the basis upon which we have made no-file decisions. And to that end, less than three -- two or three months ago the agency also inspected 3M's MDR files and complaint files and came to, at least at the close of the inspection, the conclusion that those files were adequate and the decisions were appropriate.

The 2016 FDA inspection to which Ms. Danielson refers in her testimony was a directed inspection of the 3M St. Paul and Eden Prairie facilities. A directed inspection is intended to investigate specific aspects of a facility as directed by the Center for Devices and Radiological Health (CDRH). It is clear that the direction of CDRH to the inspector was to investigate 3M MDR reporting practices related to the Bair Hugger. The 2016 inspection concluded with no significant observations identified by the inspector.

The Freedom of Information redacted FDA Establishment Inspection Report (EIR) for the 3M St. Paul facility states the following:

This inspectional assignment was requested due to CDRH receiving numerous MDRs citing litigation filed against 3M Corporation for contamination of surgical fields and subsequent patient infections from the Bair Hugger Patient Warming System (CDRH complaint #CPT1600206, dated 05/14/2015, and FDA consumer complaint #146481, dated 07/29/2016). In addition, this inspection was conducted as a follow-up to an outside complaint (FDA consumer complaint #147274, dated 09/28/2016) alleging waste heat contamination from the Bair Hugger Patient Warming System, lack of conformance to the firm's 510(k), and 3M Corporation's failure to file over 600 MDRs related to reports of patient infections. (b) (4) As no manufacturing operations related to the Bair Hugger Patient Warming System occur at the St. Paul, MN facility, inspectional coverage at this facility included design controls, complaint handling, MDR reporting, corrective and preventive actions, and field actions with a focus on the Bair Hugger Patient Warming System. Details related to these elements are described in further detail within the sections below.

As part of this CDRH directed inspectional assignment, a comprehensive surveillance inspection was conducted at the 3M Eden Prairie, MN facility from 12/05-06/2016 with a focus on the Bair Hugger Patient Warming System. This facility is responsible for assembly operations, receipt of incoming components and subsequent inspection, finished device testing, servicing and

refurbishment of returned units, and corrective and preventive actions related to production issues. Complaint handling, regulatory reporting, and design controls are handled at the St. Paul, MN facility. Further details related to the 3M Eden Prairie, MN inspection can be found in its respective establishment inspection report.

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On 12/08/2016, a closeout meeting was held with Dianne Gibbs, Infection Prevention Division Regulatory Affairs Director; Jon C. Platt, Infection Prevention Division Regulatory Affairs Manager; and (b)(6) Regulatory Affairs Specialist. Suzanne M. Danielson, 3M Health Care Business Group Vice President of Regulatory Affairs & Quality Compliance, and Mike Besser, Infection Prevention Division Quality Manager, participated in the closeout meeting via teleconference. No FDA-483, Inspectional Observations, was issued as no significant observations were made. We discussed the one late MDR and the firm's current CAPA related to late MDR reporting. In addition, we discussed FDA inspectional timeframes and medical device registration activities.

FDA will release an EIR to manufacturer if no administrative or enforcement action is contemplated, or after enforcement action is concluded.[109]

[109] Release of EIR, https://www fda.gov/downloads/aboutfda/transparency/publicdisclosure/glossaryofacronymsandabbreviations/ucm212061.pdf.

An EIR of a 2009-2010 inspection of Arizant covered the same regulatory issues as the 2016 inspection. I do not see any observations related to MDR violations in the inspection report. FDA noted the following in that EIR:[110]

> The firm has not initiated any CAPAs in response to contamination issues as no such issues have been brought to the firm's attention. A review of the complaint database from January 2006 – present did not reveal any issues with microbial air contamination as a result of using the patient warming units. It should be noted that Arizant uses a Cause Code "BG27 Contamination" (See Exhibit 4 for complaint code key) to indicate debris found within the blanket packaging. The explanation of the usage of this complaint code was provided by Dave Westlin. A query of complaints coded as BG27 did indicate it is used to code events involving foreign objects found within the blanket packaging. No microbial air contamination complaints were uncovered during the inspection. Multiple, independently-conducted studies were provided by the firm in response to the contamination inquiry. Collectively, the studies conclude the forced-air warming system does not increase bacterial contamination in the operating room. The provided studies include:

I discuss a 2010 Warning Letter from FDA later in this report but that letter concerned MDRs for complaints of burns. Reports for complaints relating to burns was resolved with FDA.

In 2015 3M communicated by letter to FDA regarding its complaint and MDR reporting practices concerning allegations of infection that were or may have been caused or contributed by Bair Huggers.[111] It is very evident to me that 3M was being proactive and transparent with FDA on the issue of allegations of infection and 3M's MDR reporting practices. As noted above the 2016 inspection was supportive of 3M's position on MDR reporting in that no observations were made by the inspector and FDA has issued no Warning Letter concerning this inspection.

Ms. Danielson's deposition refers to reporting of events that "reasonably suggest" a reportable event has occurred. The MDR regulation includes the following information on what constitutes information that "reasonably suggests" that a reportable event has occurred and who

[110] 3MBH00048072.

[111] December 14, 2015 correspondence, 3MBH02280982-02281003; November 29, 2016 correspondence, 3MBH02281065-02281067.

can determine that a device did not cause or contribute to a death or serious injury, or reportable malfunction as follows:[112]

> (c) *What kind of information reasonably suggests that a reportable event has occurred?*
>
> (1) Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
>
> (2) If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files (described in 803.18) the information that the qualified person used to determine whether or not a device-related event was reportable.

3M did not submit MDRs to FDA for the Augustine-assisted litigation complaints of infection. In order to determine whether this was reasonable and in accordance with regulations I examined the information I describe above including: (1) the 3M/Arizant FDA inspection history, (2) 3M/Arizant's history of reporting events to FDA it concluded were reportable, (3) the testimony of 3M's corporate representative and Dr. Augustine, (4) 3M's transparent correspondence with FDA and (5) FDA regulations to assess 3M's decision not to report these complaints.

It is my opinion that 3M received, reviewed and evaluated all complaints it received, including the litigation-based complaints, as required by the Quality System regulation.[113] It is my opinion that 3M appropriately did not consider the litigation-based complaints to "reasonably suggest" that a Bair Hugger may have caused or contributed to an infection. As I note above, the litigation-based complaints and associated MedWatch reports submitted by Dr. Augustine are tainted by the biased, unverified and incomplete nature of those complaints and reports.

[112] 21 CFR §803.20(c).

[113] 21 CFR §820.198.

Importantly, the FDA inspections, one as recently as 2016, did not result in any observations by leading to advisories of violations. I found that 3M has a history of submitting MDRs for events other than the Augustine generated complaints and it is evident to me that 3M is well aware of its regulatory obligations and takes them seriously. As a result, I conclude that 3M's decision to not report the Augustine generated litigation-based complaints to FDA is compliant with the MDR regulation.

8. It is my opinion that the labeling for the Bair Hugger Models 505 and 750 met regulatory requirements and are consistent with industry standards. There is no basis to find the labeling misbranded.

The Complaint and Dr. David's report allege 3M/Arizant had a duty to warn physicians and users of the risks, dangers, and adverse side effects of the Bair Huggers. The regulatory vehicle for providing instructions for use is the labeling provided with the device.

FDA regulations define the requirements for medical device labeling.[114] The FDA device labeling regulation divides devices into either over-the-counter (OTC) lay use devices or prescription devices. OTC device labeling must have "adequate directions for use" as specified in the regulation.[115] Prescription devices are exempt from adequate directions for use provided the prescription devices are properly labeled for health care professionals, they are in the possession and used under the supervision of a practitioner licensed by law to use the device, and they are prescribed by practitioners licensed in the respective state.[116] The Bair Hugger devices are prescription use only devices.

[114] Device Labeling, 21 CFR Part 801.

[115] Adequate Directions for Use, 21 CFR §801.5.

[116] Prescription devices, 21 CFR §801.109.

The labeling for a prescription device must contain information specified in the prescription labeling subpart of the device labeling regulation.[117] Prescription labeling must include a cautionary statement, the method of use of the device, as well as information for use such as indications, contraindications, side effects and precautions. A manufacturer may periodically update labeling to reflect significant new risk information when it is appropriate. . . Typically, significant new risk information can be a clinically important and distinct new type of risk or a significant increase in degree of risk.

Medical device labeling regulations do not mandate patient labeling, e.g., patient brochures or a patient insert. FDA can make patient labeling for a specific device a requirement only three ways, by a regulation promulgated under 21 CFR 801 part H, by a Premarket Application Approval order for a Class III device, or by a special control for a Class II device. FDA has not exercised any of these options to require patient labeling for Class II thermal regulating systems like the Bair Hugger devices.

Model 505 Labeling

I examined several versions of the labeling for the Bair Hugger Patient Warming System Model 505 in distribution after the clearance of the 501(k), including the following:[118]

Operators Manuals:

Doc. No. 102306H (original 510(k)), Blanket Labeling and other device labeling included. Amended by Augustine Medical letter dated May 10, 2996.

102306K: 12/1996

[117] Prescription labeling may also be called Instructions for Use or Package Inserts.

[118] 102306H: 3MBH00047301-00047384, 102306K: 3MBH00047064-00047088, 200977E: 3MBH00105180-000105193, 200977F: 3MBH00129876-00129890, 202431A: 3MBH01849567-01849585.

200977E: 2009

200977F: 4/2011

202431A: 5/2013

The labeling submitted in the 510(k) includes the requisite precautionary information (e.g., contraindications, warnings, precautions, important information), instructions for use of the device, use of blankets, maintenance, cleaning, and specifications. The warnings were amended prior to FDA clearance.

The 102306K labeling has some modifications including, for example, the use of the device name of Total Temperature Management System, discussion of hypothermia at the beginning of the manual, reformatting of instructions for use information. hose options and expanded specifications with the specification for the filtration system (0.2µm level).

The 200977E labeling is a multi-language version including an English version. The format is updated. The specifications include the same filtration system specifications and a recommended filter change of every 6 months or 500 hours of use. Safety information is updated at the end of the manual.

The 200977F version again is a multi-language version similar to the E version noted above and has expanded warnings. The 2024131A version is similar to the version 200977F and has expanded warnings and cautions

Model 750 Labeling

I examined many versions of the labeling for the Bair Hugger Total Temperature Management System Model 750 in distribution after clearance of the 510(k), including the following:[119]

Operators Manuals:

200594A dated 03/03.

200594D dated 05/05.

200742E dated 05/05.

200742F dated 5/2008

200742H undated

Service Manuals:

102346C dated 09/02

200595A dated 03/03

200595B dated 08/03

200595E dated 05/05

200595G dated 07/2009

I examined the draft labeling for the Model 750 in the cleared 510(k) from 2000 and note some differences with the labeling provided after initial distribution.[120] In no case do I think that the differences are substantial changes. The differences include the following:

[119] 200594D: 3MBH00044582-00044598, 200595E: 3MBH00044599-00044626, 200742E:3MBH00044655-00044864, 200595G: 3MBH00044489-44519, 200742H:3MBH00044865-00044882, 200594A:3MBH00044900-00044917, 200595A:3MBH00044918-00044947, 102345D:3MBH00044580-00044581. 102346C:3MBH00044199-00044228, 200595B:3MBH00044165-00044193.

[120] 3MBH00047037-00047057.

1. The 2000 draft labeling describes hypothermia.

2. The 2000 draft indications are more specific in regard to hypothermic symptoms. In addition introductory information states:

> Examples of current applications for the Bair Hugger Total Temperature Management system are post anesthesia care units (PACU), recovery rooms, operating rooms, emergency departments, obstetrical suites, and intensive care areas.

The comparison of substantial equivalence also refers to OR use as follows:[121]

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients

3. The Model 241 fluid device warning in the 2000 draft is not identical to the recent labeling.

4. There is a warning on mounting the device in the 2000 draft labeling and it was changed to a Caution.

5. There is more information on the Model 241 warmer and blankets in the 2000 draft labeling.

6. "Important Information" in the 2000 draft labeling is relocated in the recent labeling.

[121] 3MBH00047009.

7. The "Read Before Servicing" information in the original draft labeling is restructured in the recent labeling.

As noted earlier in this report, FDA cleared two labeling changes for the Bair Hugger in submissions K041686 and K053645, based on my search of FDA's 510(k) database and litigation production.[122] The K041686 record shows this was a special 510(k) "to include results and recommendations regarding the benefits of forced air warming from published studies by a number of medical experts."[123] Similarly, the second special 510(k) submission, K053645, was to add labeling claims.[124] It is clear from the record that FDA reviewed the claims thoroughly and requested additional information, which Arizant submitted.

As I stated I do not believe that the differences in labeling between the original draft labeling and the marketed devices are significant. There is no need to describe hypothermia in detail in the Bair Hugger labeling since the device is for prescription use only. Users should refer to labeling for the Model 241 fluid warmer and blankets. The other changes are minor edits of information.

I examined the labeling for blankets used with the Bair Hugger. The labeling states words such as the following:[125]

2 Remove the backing from the surgical tape and tape the blanket to the patient. The surgical tape prevents air from flowing toward the surgical site (see Figure B).

[122] http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

[123] 3MBH00047643.

[124] 3MBH00047738.

[125] Blanket labeling example: 3MBH00045472-45474.

This Complaint alleges that Bair Huggers caused surgical site infections. Expert for Plaintiffs, Dr. Yadin David, opines on page 41 of his report that "...the removal of an airborne contamination warning from the Bair Hugger [labeling] makes the device unreasonably dangerous." He notes that the Model 200 had a warning and the 500 and 700 series devices do not have such a warning. To address this I evaluated factors related to the air filtering in the Bair Hugger Temperature Management System.

Labeling instructions refer to isolation of the blankets from the surgical site using tape.[126] The air supplied to the blankets is filtered by a 0.2µm filter. The material of the disposable blankets themselves may afford some degree of air filtering although the filtering contribution of the blanket material is not established in the litigation records.

A 3M Risk Management Report indicates a low risk level for the potential hazard of surgical site infection.[127] Mr. Van Duren's testimony was consistent with this 3M risk analysis when asked about the absence of the prior Model 200 labeling statement as follows:[128]

And it's very likely that the hazard analysis that occurred subsequent to the development of this device recognized that the risk index was either too low or zero and removed that warning from the labeling.

[126] 3MBH00047031 and 3MBH00047032-00047033.

[127] 3MBH00553184.

[128] Van Duren deposition, 3/7/17, Page 314:14-18.

Dr. David also includes in his report what he characterizes as a Warning on airborne contamination, from labeling for a product called Mistral-Air Plus.[129] The Bair Huger Model 750 is a predicate for the Mistral-Air Plus device.[130]

The Mistral-Air Plus statement is not a Warning but rather stated in Mistral labeling to be a "Safety Precaution," therefore, Dr. David's reference to FDA guidance on Warnings regarding the Mistral-Air Plus labeling is misplaced. The Mistral-Air Plus Safety Precaution states:

The Mistral-Air® Plus warming unit is fitted with an air filter; however airborne contamination should be taken into consideration when using the warming system.

A precaution is a statement of special care to be exercised by the practitioner for safe and effective use of the device.[131] The above Mistral-Air Safety Precaution statement is unclear concerning what considerations should be made regarding airborne contamination and does not provide the user with actionable steps to take. The Mistral-Air brochure and accessory usage indicate the Mistral-Air can be used in an operating room. However, no Mistral labeling information provides factors to consider when using the device in an operating room environment.

According to FDA, a Warning in labeling may be appropriate if there is reasonable evidence of an association of a serious hazard with the use of the device.[132] I do not believe that a Warning in the Models 505 and 750 labeling regarding an infection risk for the Arizant forced air warming devices and accessories when used in operating rooms was warranted due to: (1)

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[129] See also http://www.the37company.com/product_overview/forced_air_warming_1/warming_unit.

[130] https://www.accessdata fda.gov/cdrh_docs/pdf10/K101705.pdf. Page 41 of David report.

[131] K91-1 FDA guidance.

[132] FDA Guidance, http://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081368 htm.

the paucity of MDR reports pertaining to infection until Dr. Augustine induced reports began in 2015 and 2016 that I discuss in this report, (2) the lack of a direct causal relationship of infections to forced air warming that Dr. David acknowledges in his report (p. 31), (3) the analysis of risk of surgical site infections in the 3M Risk Management Report noted above, and (4) the existing blanket and taping design and blanket labeling, and filter mitigations described above .

I find as I describe above that the draft labeling in the original 510(k) and the labeling in the subsequent versions of the Model 750 all meet the FDA prescription labeling requirements of 21 CFR §801.109. The labeling for the Model 505 also meets the regulatory requirements for prescription labeling. The labeling is also consistent with industry standards in form and content.

As noted above, the labeling for the blankets includes taping instructions to prevent airflow to the surgical site. The existing Warnings are consistent with predicates and the current published data and are acceptable.

FDA never requested any modifications or additions to the labeling for the Models 505 or 750 or any other Bair Hugger model at any point in time.

Given that the Bair Hugger Models 505 and 750 labeling conforms to the prescription device regulation I believe there is no basis to allege that it is misbranded.[133] Dr. David does not opine that the Bair Hugger labeling contains false or misleading information and I did not identify any such information in my evaluation of the labeling.

[133] Misbranding and adulteration and other prohibited acts under the FDCA are charges brought by FDA through the Department of Justice based on evidence described in FDA's Regulatory Procedures Manual. The charges are subject to due process and are adjudicated in federal court.

9. It is my opinion that a 2010 Warning Letter from FDA to Arizant, Inc. did not result in any observation regarding MDRs for complaints of infection and the findings in the letter which were quickly resolved does not undermine the reasonable assurance of safety and effectiveness of the Bair Hugger.

On June 7, 2010, FDA issued a Warning Letter, under my signature as Director of CDRH Compliance, to Arizant Inc. based on an inspection of Arizant's Eden Prairie, Minnesota facility from November 30, 2009 to January 6, 2010.[134] This inspection is one of the regulatory events Dr. David finds to be troubling. I do not find the inspection to be troubling whatsoever but instead a rather typical directed inspection with quick resolution of the citations in the FDA letter.

The 2010 Warning Letter cited four violations of the Medical Device Reporting regulation, 21 CFR Part 803, and a violation of the Corrections and Removal regulation, 21 CFR 806. The letter included examples of each violation and an analysis of Arizant's January 20, 2010 response to the Form 483 issued to Arizant at the close of the inspection.[135] The letter also includes comments on an Arizant complaint management procedure. Arizant Inc. adequately responded to FDA's Warning Letter and FDA closed out the inspection and Warning Letter on July 27, 2010.[136]

The Warning Letter cites no violations of the FDA quality system regulation, 21 CFR Part 820. As I noted earlier in this report the Quality System regulation is intended to ensure that

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[134] http://wayback.archive-it.org/7993/20161023102048/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm217747 htm..

[135] Form 483 is a list of observations made by the FDA inspector during the inspection and presented to the most responsible person of the inspected facility at the close of the inspection. The observations are not violations but form the basis for an Establishment Inspection Report that includes recommended violations. The final decision on violations rests with the Director of Compliance, CDRH or as delegated by him/her to District Directors. See FDA Regulatory Procedures Manual, http://www fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/default htm.

[136] http://www fda.gov/ICECI/EnforcementActions/WarningLetters/ucm235588 htm.

finished devices will be safe and effective.[137] The Warning Letter did not lead to FDA enforcement action against Arizant Inc. based on my review of FDA enforcement actions on FDA's web site.[138]

At the end of the inspection in January 2010 Arizant responded quickly to the five observations, correcting four observations before FDA issued the Warning Letter.[139] Two observations related to filing an MDR report, which Arizant submitted. Arizant adequately responded to the one Corrections and Removal observation. Arizant submitted to FDA a report of a correction and removal (i.e., 806 Report) for power cords manufactured and supplied by Electri-Cord Manufacturing Corporation and used on Arizant devices. No Arizant manufactured components were implicated, based on my review of the FDA recall database.[140]

One issue in the FDA inspection dealt with the reporting of MDRs for burns. FDA changed its opinion on reporting burns between the early 90s and the 2009-2010 date of the inspection. The inspection report notes the following:[141]

> and he provided me with a letter addressed to the U.S. Food and Drug Administration dated May 7, 1992 (Exhibit 19). The letter outlines burn severity from first to third degree. Arizant's policy has been to report only 3rd degree burns.
>
> CALL 63505 (Exhibit 20) was received on 04/13/06 and involved a patient who sustained 2nd degree burns; the patient was subsequently moved from the surgery center to the ER where the burns were treated. An Initial Adverse Event/Injury Report form, AMI148, was completed by an Arizant customer service rep (page 2). In addition to the hospital reporting the incident, on May 18, 2006 the patient personally contacted Arizant via the website contact feature. The patient stated she 'ended with third degree burn on my left breast" and inquired about the product (page 4).
>
> [NOTE: During the inspection, I double-checked my interpretation of the regulation with Linda Hoffman, Consumer Safety Officer, FDA/CDRH/Division of Surveillance Systems. She confirmed that this event should have been reported.]

[137] 21 CFR §820.1(a).

[138] FDA Enforcement Reports, http://www fda.gov/safety/recalls/enforcementreports/.

[139] establishment inspection report, 3MBH00048067-00048085.

[140] http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[141] 3MBH00048075.

Page 4 of the Establishment Inspection Report (EIR) for this inspection refers to the Bair Hugger containing a 0.2µm HEPA filter.[142] The EIR does not describe the basis for this statement. There is no evidence that Arizant mislead FDA on this issue. As noted in this report, FDA was informed of the status of the filter in the Model 750. Since this was a directed inspection to evaluate complaints and MDR reporting and not to evaluate the design of the device the characteristics of the filter are really not germane to the inspection in any case. I discuss the published papers provided to the inspector in a subsequent comment on Dr. David's report.

I do not believe that the Warning Letter undermines the safety and effectiveness of the Bair Hugger. Warning Letters are advisory actions allowing companies the opportunity to take voluntary action to improve their quality management program.[143] Arizant responded to the issues in the letter by addressing certain limited MDR issues, correcting a complaint procedure, and submitting 806 reports for power cords. If FDA believed the Bair Hugger was a risk to health or warranted corrective action FDA could have proceeded to an enforcement action. FDA did not do so. The Bair Hugger continues to be marketed by 3M, based on my review of 3M's web site, and 3M is legitimately permitted to do so by the 510(k) clearance orders from FDA.

10. It is my opinion that in a 2012 Warning Letter to Augustine Biomedical & Design, LLC the FDA repudiated claims against the Bair Hugger made by Augustine Biomedical & Design, LLC.

In a Warning Letter dated July 27, 2012, FDA informed Augustine Biomedical & Design, LLC that an infection reduction claim and comparative claim "HOTDOG IS SAFER" for its Hot Dog Patient Warming System represented a major change or modification to the intended use of

[142] 3MBH00048067-00048085.

[143] See FDA Regulatory Procedures Manual, Section 4-1.

the device.[144] FDA informed Augustine Biomedical & Design, LLC that the Hot Dog Patient Warming System was adulterated and misbranded and such a change required submission of a new 510(k) for the Hot Dog Patient Warming System and the claims require submission of clinical data to support the claims.

The claims found by FDA to be violative refer to the Hot Dog Patient Warming System advantages compared to forced-air warming, air-free warming, and the statement "Bair Hugger contaminates sterile field: Waste hot air convection currents transport contaminated air into the surgical site. Air-free warming has no such effect. Researchers concluded: Airfree warming, therefore, is recommended over forced-air warming for orthopedic procedures."

The FDA web site indicates a response letter by Augustine Biomedical & Design, LLC was not posted and there is no FDA close out posted on the web site. I see no FDA-cleared 510(k) for the Hot Dog Patient Warming System since 11/23/11.[145] Therefore, I must conclude that FDA still has not agreed with the claims.

The claims noted above made by Augustine Biomedical & Design, LLC against the Bair Hugger run counter to the preponderance of evidence of the safety and effectiveness data and information previously submitted by Augustine Medical Inc. to FDA in the 510(k)s for the Model 750[146] in the medical literature previously referenced in this report, the ECRI analysis and as provided to FDA in 2015.[147]

[144] http://www fda.gov/iceci/enforcementactions/warningletters/2012/ucm315670.htm.

[145] Search 5/11/17, http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

[146] See K041686 and K053645 and FDA review of the last submission.

[147] 3MBH01630129-01630651. ECRI analysis in this document as well.

In my review of MDRs in my report I identified MDRs for the Hot Dog related to overheating of the device and a report of patient injury. This is further evidence undermining the alleged comparative superiority of the Hot Dog over the Bair Hugger.

11. It is my opinion that CDC/HICPAC and FDA meeting discussions concerning a heater-cooler device are unrelated to forced air warming devices.

Dr. David refers to a 2015 Centers for Disease Control and Prevention/Healthcare Infection Control Advisory Committee meeting in his allegations regarding the Bair Hugger (Page 43). I believe his characterization of a statement from the meeting must be considered in context to understand that the focus of the CDC/HICPAC was not on forced air warming devices.

In the meeting of the CDC/HICPAC in November 2015 there was a presentation by Drs. Perz and Bell, two CDC employees who were not members of HICPAC entitled "Nontuberculous Mycobacterium Infections Associated with Heater-Cooler devices."[148] The particular heater-cooler device type in question circulates temperature-regulated water in cardiovascular surgery and is a different classified type of device compared to temperature regulating devices like the Bair Hugger. The presentation section of the report to HICPAC on the heater-cooler device type includes a statement without attribution, "The heater-cooler unit appears to be harmless from an infection perspective, but the water overflow bottle is likely rarely, if ever, sanitized and is situated in front of a fan. Nothing that blows air should be in an operating theater, if possible." This statement is not in the discussion section of the report and is

[148] https://www.cdc.gov/hicpac/pdf/mm/November%205-6%202015HICPAC-Meeting_Summary_Final-508.pdf.

not characterized as a conclusion of HICPAC as stated in the undated and untitled report by Dr. William Jarvis, expert for Plaintiffs.

FDA's posted a safety communication on circulating water heater devices on October 25, 2015.[149] FDA posted no safety alert pertaining to other types of temperature regulating devices.

In March 2016 the CDC/HICPAC was brought up to date by an FDA employee on its activities pertaining to the heater-cooler devices used in cardiac surgery. The HICPAC minutes state, in part:[150]

Many challenges are associated with this multi-factorial problem.

- It is not feasible for these devices to be sterile.
- There are many OR environment considerations as well as hospital infection control procedure and patient considerations.
- NTM is fairly ubiquitous and, locating the source of NTM leading to infection is challenging.
- It is not clear whether there is an acceptable level of contamination at which a device can still be used safely. For instance, if aerosols can be reduced or eliminated from the unit, can the circuit water safely maintain some level of contamination?
- There are challenges associated with validating the cleaning and disinfection procedures and what might represent "worst-case" testing. It is not clear how real-world use can be mimicked in laboratories for testing. Which microbe or microbes should be monitored and what is an acceptable output or contamination level?
- Heater-cooler units are a capital expense, currently with a service life of approximately 10 years. If they become contaminated beyond an acceptable level, alternatives are needed for these lifesaving devices. Unless contaminated units can be reliably disinfected, purchase of new units may be necessary.
- Patient notification is a challenge, including what patients should be told regarding the risks prior to a procedure and whether patients who have already undergone a cardiac surgery should be stratified and notified based on a reliable risk scale.

FDA posted a web site pertaining to the heater-cooler devices used in cardiovascular surgery. It does not pertain to temperature regulating devices like the Bair Hugger.[151] FDA

[149] https://www fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963 htm.

[150] https://www.cdc.gov/hicpac/pdf/mm/March-31-2016-HICPAC-Meeting-Summary-FINAL.pdf.

posted a safety communication on June 1, 2016, regarding one specific heater-cooler device used in cardiovascular surgery and updated that communication on October 13, 2016.[152]

An update at the July 2016 meeting of CDC/HICPAC continued to focus on the cardiovascular heater-cooler units discussed in prior meetings.[153] CDC's MMWR Report dated October 14, 2016 continued to focus solely on the heater-cooler devices used in cardiovascular surgery.[154]

There is no substantive discussion in the CDC/HICPAC minutes of risks posed by other types of temperature regulating devices like the Bair Hugger.

12. It is my opinion that Arizant appropriately monitored the literature and other sources of information regarding its products and investigated concerns regarding its device in accordance with FDA post market procedures and industry practice. Arizant also conducted field actions based upon postmarket information as appropriate.

It is the responsibility of a manufacturer to evaluate and investigate complaints regarding their device.[155] A manufacturer is also responsible for monitoring information regarding its device and to take corrective and preventive action when necessary to mitigate device risks.[156] 3M/Arizant complied with their postmarket regulatory duties in a manner consistent with a reasonable and prudent manufacturer.

Dr. Augustine made various claims against the Bair Hugger devices after he formed a

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[151] https://www fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm.

[152] https://www fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213 htm

[153] https://www.cdc.gov/hicpac/pdf/mm/July-14-15-2016-HICPAC-Summary-FINAL.pdf.

[154] https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w.

[155] Complaint files, 21 CFR §820.198.

[156] Corrective and preventive action, 21 CFR §820.100.

new, competing company.[157] In a regulatory context I would characterize his assertions concerning forced air warming as complaints. There were also publications, by far mostly supportive and some adverse to forced air technology.[158] I have reviewed the correspondence between Dr. Augustine, Arizant and 3M following his departure from Arizant.[159] I have also reviewed marketing claims and scientific literature supported by Dr. Augustine and his company Augustine Biomedical and Design and for Arizant.[160]

Arizant evaluated the "Blowing Air is Risky" campaign by Dr. Augustine.[161] Arizant notes the following in its analysis:

> **Summary:** ABAD has promotional literature and a new web site (www.blowingairisrisky.com) that makes claims about forced air warming. They say that 1) warming unit haves internal contamination, 2) this contamination is blown onto patients, 3) the contamination is uncleanable, and 4) the units cause "noise pollution. These assertions are based on sloppy or deceptive readings of medical literature, unpublished research of their own, and video-based product demonstrations. We have extensive research and real-world experience refuting these claims.

Based on my review of the documents concerning Dr. Augustine allegations, 3M/Arizant responded appropriately in evaluating the merits of Dr. Augustine's claims of contamination and infection caused by the Bair Hugger. As I discuss in this report, 3M/Arizant ultimately came to the conclusion that Dr. Augustine's claims were not scientifically supported. The FDA's 2012 Warning Letter to Dr. Augustine I discuss in this report affirms the reasonableness of the company's conclusions with respect to Dr. Augustine's claims.

In no case did I find evidence of Arizant disregarding any other complaints or

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[157] Example, 3MBH00001186-00001188.

[158] Studies and associated emails distributed throughout the productions: Examples 3MBH00001701-00001807, 3MBH00002393-0002429, 3MBH00005698-00005702.

[159] Examples, 3MBH00005676-00005677, 3MBH00043532, 3MBH00005688, 3MBH00005693-00005697, 3MBH00030543-00030549, 3MBH00030552-00030556, 3MBH00034432-00034438, 3MBH00038869-00038871.

[160] Examples, 3MBH00040177, 3MBH00078167-00078168, 3MBH00078181-00078184.

[161] Example, 3MBH00001692.

information they became aware of regarding their device or the technology upon which it is based. Instead, it appears from my review of the records, that they took these complaints and information seriously and responsibly investigated them.

There are several additional examples of Arizant's follow up regarding allegations of infections. Arizant followed up with Dr. Beavers on her article in the Kentucky Epidemiological Notes and reports in 2007 cited by an Augustine promotional piece. Dr. Beaver stated the following:[162]

> I am writing to clarify some points made in an article I wrote for the *Kentucky Epidemiologic Notes & Reports* in March, 207. In the article I discussed our findings of investigations we performed into outbreaks of *Acinetobacter* at two acute-care hospitals in Kentucky. As you may know, during such investigations we evaluate many factors which may be associated with infection. Therefore, during our investigation we collected data to evaluate whether forced air systems such as Bair Huggers were associated with *Acinetobacter* infection. We did not find an association between *Acinetobacter* infection and Bair Hugger or forced air system use at either facility.
>
> In addition, the Falagas article cited in the paper does not describe forced air systems such as Bair Huggers to be infection reservoirs. The important point of the article and investigation we performed was that a variety of items used during care of ill patients may become contaminated with *Acinetobacter* or other microorganisms. In this investigation, for example, mechanical ventilation was associated with Acinetobacter infection. Therefore, in caring for hospitalized patients, the most important means of preventing infection is to practice good infection control procedures such as hand-washing and environmental cleaning. Conversely, we found no evidence that avoidance of the use of products such as forced air systems would prevent infection with *Acinetobacter*.

Arizant interacted with the British regulators concerning alleged adverse performance of forced air warming.[163] They sent the British regulators a detailed letter dated August 7, 2008, concerning Dr. Augustine's claims made to NICE.[164]

Arizant corresponded with its customers regarding concerns about use of the Bair Hugger. One hospital publicly disputed Dr. Augustine's allegations that the Bair Hugger could lead to increased infections.[165]

Arizant is required by regulation to submit reports of corrections and removals to FDA.

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[162] Augustine article 3MBH00001186-00001188. Dr. Beavers paper, 3MBH00000932-00000937, Dr. Beavers response 3MBH00000930.

[163] 3MBH00002104-00002188.

[164] 3MBH00002183-00002186.

[165] Examples, 3MBH00001526 and 3MBH00001532.

A correction is when a manufacturer makes a change to a device while keeping it at its point of use and a removal is a retrieval of a device in both cases in order to reduce a risk to health or to remedy a violation of FDA law or regulations.[166] A correction or removal may be a recall and FDA classifies recalls. There are three classes of recalls, Class I, II, or III, with Class I being the most serious. FDA defines a Class II recall as "a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote."[167] FDA posts recall actions on its web site. So, any voluntary recall actions by Arizant classified by FDA can be identified.

I examined the FDA recall database[168] using the terms "Arizant" and "3M."[169] The search revealed seven recall listings. One recall was a 2005 Class II recall for the Model 555 pediatric blanket.[170] Another recall with two listings was a 2007 Class II recall for Ranger warming sets.[171] The third recall with four listings was in 2010 for power cords.[172] There are no recalls listed for the Models 505 or 750.

The above are but a few examples of many appropriate actions by Arizant to respond to concerns regarding their devices. In sum, I think that Arizant properly reacted to the concerns of customers and to Dr. Augustine's claims in a reasonable and prudent manner according to FDA postmarket requirements. I am not aware of any representations made by 3M or Arizant with

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[166] 21 CFR Part 806.

[167] 21 CFR §7.3(m)(2).

[168] http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm.

[169] Search dated 4/21/17.

[170] http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=37753.

[171] http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=53634 and http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=53633.

[172] first of four listed, http://www.accessdata fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=88575.

regard to the Bair Hugger device that misrepresented the safety of the device. As I document above Arizant also conducted field actions as appropriate based on postmarket information.

13. Additional rebuttal to the opinions in the report by Dr. Yadin David

Dr. Yadin David submitted an undated report on behalf of Plaintiffs. I have commented on some aspects of his report in my foregoing opinions. This section includes additional rebuttal to his opinions.

First, I wish to disclose my prior interactions with Dr. David while I was an employee of the FDA. I interacted with Dr. David for a period of time when I was the Director of the Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices (DAGID), Office of Device Evaluation, as the division was called prior to my appointment as the Director, Office of Compliance, Center for Devices and Radiological Health in 2003. In my role as DAGID Division Director I reviewed candidates for new committee member appointments to the FDA advisory committee panels associated with the devices evaluated in DAGID. Medical device committee members provide independent advice to FDA on issues related to medical devices. The committee members are technically qualified experts in aspects of their field.[173] They are not appointed based on regulatory expertise. Regulatory advice and counsel at panel meetings is provided by the panel executive secretary, an FDA employee, and by the attending FDA division manager seated with the panel.

If my memory serves me well, FDA appointed Dr. David to the General Hospital Advisory Committee Panel during my tenure as DAGID Director. The Device Good Manufacturing Practice Advisory Committee (GMP Committee) he refers to on page 3 of his

[173] Advisory Committees, http://www fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/ucm117646 htm.

report is an advisory committee associated with the Office of Compliance, CDRH. The GMP Committee was inactive from approximately 1995 until 2013 when in April 2013 FDA asked the GMP Committee to evaluate the quality system regulation and the issue of meeting the challenges of extreme weather. Dr. David was not a member of the GMP Committee at that meeting.[174] There have been no meetings of the GMP Committee since April 2013. He was appointed Chair of the GMP Committee with a term beginning 12/10/2014.[175] As I recall, I had no interactions with him while I was Director of the Office of Compliance, CDRH from 2003 until my retirement in 2011.

1. Dr. David characterizes his report as a Hazard Analysis and discusses medical device hazard analysis and risk mitigation on page 5 of his report. It may be implied in Dr. David's report that all risks require exhaustive mitigation. This is not the case. Risks that are acceptable given the existing risk control measures, i.e., the severity and probability are within predetermined acceptable limits, do not require additional mitigation.[176]

Furthermore, I do not find Dr. David's Hazard Analysis to be in a form or manner of an industry standard medical device hazard analysis consisting of a risk assessment and risk control evaluation. It does not contain a systematic identification of characteristics related to the safety of the Bair Hugger, identification of all reasonably foreseeable hazards, estimation of risks, an evaluation of risk reduction when required for all hazardous situations by predetermined criteria and quantitative methodology, e.g., FMEAs, FTAs, an appropriate and practicable risk control

[174] GMP Committee Roster 4/11/2013, http://www fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/UCM347410.pdf

[175] GMP Committee Roster, http://www fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/DeviceGoodManufacturingPracticeAdvisoryCommittee/ucm124607 htm

[176] See ISO 14971, Section 6, Risk Control.

option analysis based on valid scientific principles, residual risk analysis, and risk/benefit analysis.[177] Instead it is a qualitative expert report on the use of the Bair Hugger in orthopedic surgery commenting and based on the regulatory process, FDA inspections, his practice of assessment of technology, selected publications, and other aspects.

2. On page 5 he refers to the principle of safety and the Hippocratic Oath. What is relevant to this litigation is the definition of "safe" as described in FDA regulation. It is the FDA standard upon which FDA determines the safety of the Bair Hugger and the standard a device must meet. While Dr. David focuses almost entirely on risk in his report the determination of safety is an assessment of benefit/risk and the absence of unreasonable risk. I do not see assessment of risk/benefit in his report per the regulatory definition of safe. He ignores the benefit side of the equation. The FDA definition states:[178]

> There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

3. On pages 6-16 Dr. David discusses his laboratory process for assessing the "basic operation and mechanisms" of a Model 750 device he purchased on e-Bay.com. He also states "his investigation was to examine a Bair Hugger from a biomedical engineering perspective to determine if the design and function of the device posed a risk to patient safety." He states two

[177] See ISO 14971.

[178] 21 CFR §860.7.

ways the Bair Hugger could pose a risk, i.e., (1) disruption of the OR ventilation system and (2) bacteria from the device being introduced into the operating room currents. The conclusions of his report cannot rely on his examination of the e-Bay device because he did not perform any disruption of air flow study or bacterial examination of the device and its outflow in a simulated OR with the device used as intended. Any studies would not be valid in any case since the device he obtained could not be established as representing a serviced device currently in use in a hospital OR or otherwise obtained from the manufacturer for immediate use in an OR.

His report does not include any details of the protocols and test methodologies he employed nor the location of his examination so his findings must be discounted.

His examination does not meet the requirements for control of samples for examination and investigation requirements in the FDA Investigations Operations Manual.[179] Therefore, his examination and resulting conclusions based on his examination would be rejected as a basis for possible enforcement action by FDA.

4. I agree with Dr. David on page 16 that risk classification and controls "insure the safety and effectiveness of the device." He discusses Class III devices that are subject to "rigorous approval" but he does not assess in his report the contents of the 510(k)s for the Bair Hugger Models 505 and 750 that are Class II devices cleared by the FDA and are therefore controls to "insure the safety and effectiveness of the device."

5. Dr. David refers on page 18 to the General Accounting Office and Institute of Medicine reports that made statements such as "FDA lacks the capacity to provide adequate review and clearance oversight. . . ." In regard to medical device evaluation and enforcement I disagree with this statement. In my experience while a manager in the CDRH Office of Device Evaluation and

[179] https://www fda.gov/ICECI/inspections/IOM/default.htm.

the CDRH Office of Compliance for the time period 1990 through 2010 I am unaware of a lack of resources in those offices preventing or limiting FDA's ability to properly and effectively promote and protect the public health. As workload changed, FDA was quick to redirect resources to the Office of Device Evaluation and the Office of Compliance from other offices in order to maintain necessary staffing and expertise. FDA supplements its staff with the expertise of its Advisory Committee, fellows, and other special government employees.

Dr. David also states that "it is the manufacturer's responsibility to ensure its devices are safe, labeled and marketed in accordance with the approved or cleared indications for use." He also states "FDA relies on the assurances of the manufacturer that appropriate performance testing and validation has occurred." This is not accurate. FDA has a corresponding responsibility to ensure that devices on the market are safe and effective. His report and mine refer to FDA's continuous oversight of Augustine Medical and 3M/Arizant throughout the life cycle of the Bair Hugger devices including, for example, premarket evaluations, facility inspections, Warning Letters, and postmarket evaluations of trade complaints submitted to FDA by both Dr. Augustine and 3M/Arizant.

6. On page 19 Dr. David refers to the Least Burdensome Provisions and their application to 510(k)s. In fact, these provisions apply to both 510(k) and PMA devices.[180] While FDA's evaluation of substantial equivalence is the focus of a 510(k) review FDA can request any information it requires in order to render a decision on equivalence and can assess the impact of evolving science, medicine and engineering on the evaluation of equivalence.

7. On page 19 he begins a discussion on the Bair Hugger's 510(k) clearance history. His comments display a fundamental lack of knowledge of the 510(k) process.

[180] https://www fda.gov/RegulatoryInformation/Guidances/ucm085994 htm.

He refers to the Sweetland Bed Warmer predicate identified in the 510(k) for the Bair Hugger Patient Warming System cleared by FDA in 1987 (K873745).[181] This Bair Hugger model (Series 200) was intended for postoperative patient warming using a Bair Hugger Cover on the patient. He questions the validity of the Bair Hugger 500 and 700 series models use in operating rooms given that the Sweetland device and Model 200 were not labeled for use in operating rooms. Dr. Yadin states that the Sweetland Bed Warmer "was never used as a means to create normothermia during surgical procedures, as later Bair Hugger models were." He also mentions changes in technology in the Bair Hugger devices.

The predicate for the Model 500 is the Patient Warming System Model 200 (K873745) in which Sweetland is identified. The predicate for the Model 505 is the Model 500.[182] The 510(k) submission for the Model 500 included valid scientific evidence of the Bair Hugger's use in operating rooms.[183] The 510(k) for the Model 505 clearly states that one intended setting where the Model 505 could be used is in operating rooms.[184]

Contrary to Dr. David's belief, the Sweetland device is a legitimate predicate in the lineage of the Models 500, 505 and 750. The change in the Bair Hugger claims, the clinical usage of the Bair Hugger in operating rooms, and technological changes of the Bair Huggers over time were all legitimately enabled by 510(k) clearances.

The intended use of the Bair Huggers has actually not changed since the clearance of the 510(k) for a Model 200 series device. The intended use of Bair Huggers has always been

[181] 3MBH00047858-00047864 and https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K873745.

[182] 3MBH00047382-00047383. Model 505 is predicate for Model 750.

[183] 3MBH00047446.

[184] 3MBH00047197.

warming of patients. FDA has made clear the meaning of the term intended use. FDA guidance states:[185]

> For purposes of substantial equivalence, the term **intended use** means the general purpose of the device or its function, and encompasses the indications for use. The term **indications for use**, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.[22] The intended use of a device is one criterion that determines whether a device can be cleared for marketing through the 510(k) process or must be evaluated in a PMA (or alternative submission type), or if appropriate, a *De Novo* request. The proposed labeling in a 510(k) is used to determine a device's intended use (Section 513(i)(1)(E) of the FD&C Act). The indications for use statement in a 510(k) is also a factor in determining a device's intended use. Consistency between the indications for use statement and the proposed labeling will facilitate the review of the 510(k).
>
> A finding of substantial equivalence means that the indications for use of the new device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use. For devices with general indications for use that do not specify a disease, condition, or population (or an anatomical site from which a disease state or population may be inferred), the indications for use and intended use are the same. Such indications for use are referred to as "tool type" indications for use. Examples of devices with "tool type" indications for use include devices such as scalpels, which are often indicated for cutting tissue, or imaging devices, which are often indicated for taking images of the body. A scalpel indicated for removing a particular type of cancerous cell, however, has indications for use specific to the identified disease, condition, or population, and therefore, does not have "tool type" indications for use.
>
> ***
>
> While a new device must have the same intended use as a predicate device in order to be SE, the Center does not require that a new device be labeled with precise therapeutic or diagnostic statements identical to those that appear on predicate device labeling in order for the new device to have the same intended use. Label statements may vary. Certain elements of a predicate device's labeled indication may not be critical to its intended therapeutic, diagnostic, prosthetic, surgical, etc., use. The Center's scientific expertise enables it to exercise considerable discretion in construing intended uses in the labeling and promotional materials for predicate and new devices.3/ Thus, a new device with the same intended use as a predicate device may have different specific indication statements, and, as long as these label indications do not introduce questions about safety or effectiveness different from those that were posed by the predicate device's intended use, the new device may be found SE.

As stated above by FDA, an intended use is the general functional purpose of a device. In the case of the Bair Huggers the indication is a "tool type" use. Since the functional or "tool type" purpose, i.e., patient warming, of the Bair Huggers did not change then all the Bair Hugger

[185] 2014 guidance, https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf and 6/30/86 K86-3 guidance superseded by 2014 guidance.

devices were equivalent on this basis. The expansion of clinical settings for use of the Bair Huggers is legitimately encompassed by the Bair Hugger intended use.

The technological characteristics of a new device can change from that of a predicate and FDA can find the new device to be equivalent as long as the differences in characteristics do not raise new types of safety and effectiveness questions, there are accepted methods to assess the changes, and the performance data demonstrates that the new device is equivalent to the predicate. FDA states the following:[186]

> After FDA has determined that a valid predicate device exists for a new device and that both devices have the same intended use, FDA will move to Decision Points 3 and 4 of the Flowchart (see **Appendix A**). In these steps of the 510(k) review process, FDA compares the technological characteristics of the new device and the predicate device to determine whether the new device has the same technological characteristics as the predicate, and if not, whether the different technological characteristics raise different questions of safety and effectiveness.[25] Devices reviewed under the 510(k) program commonly have different technological characteristics from their predicate device(s); however, FDA rarely makes a finding of NSE at Decision Point 4.[26]
>
> ***
>
> If a new device has the same intended use as a predicate device, and there are no technological differences between the new and a predicate device, the new device is SE. If the device has the same intended use and technological differences, but the technological differences could not affect safety or effectiveness, it is SE. If the device has the same intended use and technological differences that could affect safety or effectiveness, the new device may not be SE. Technological differences may include modifications in design, materials, or energy sources; for example, changes in the power levels of electrical surgical instruments, the use of new reagents in in vitro diagnostic devices, the use of new materials in orthopedic implants, and the use of new battery designs in implanted pacemakers. The Center finds devices with new technological features to be NSE when the new feature could adversely affect safety or effectiveness in a way that is consequential under the conditions of intended use.

There was a progression of technological changes in Bair Huggers over time as evidenced in the 510(k)s I identify in this report. None of the technological changes raise new types of safety and effectiveness questions and standards-based or state of the art test methodologies enabled assessment of the changes. The Bair Huggers 510(k)s included evidence that the devices performed as intended, met safety standards and were certified by recognized test facilities.

[186] Id.

There were no FDA Quality System design control requirements prior to 1997, including, for example, the requirements for a manufacturer to establish and maintain a design history file and control of design changes. Therefore, Dr. David cannot retrospectively apply the FDA design control requirements to the development and testing of the Bair Huggers before FDA's transitional enforcement discretion period on design controls expired on June 1, 1998.[187]

Nevertheless, prior to the development of the QS standard and the original version of the International Standard on risk management, ISO 14971, Augustine Medical applied design control and risk management methodologies in development of the Bair Hugger.[188]

8. Beginning on page 19 Dr. David refers to the Model 505 Summary of Safety and Effectiveness.[189] He takes issue with the statement in the Summary and the papers submitted concerning contamination. The Summary, in part, states the following:

> C. Other Safety Concerns:
>
> 1. Contamination. Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.
>
> Prevention of airborne contamination: All Bair Hugger® Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site. Additionally, air is filtered through a 0.2 micron filter. Two studies have concluded that the Bair Hugger® 500 Series Units (that have the same air output specifications and the same filter density as the Model 505) do not increase the incidence of microbial or wound contamination[4,5].
>
> ***
>
> 4. Hall, A. Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
>
> 5. Zink, RS. Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.

[187] Final QS regulation FR Notice, https://www fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127 htm.

[188] Risk management and design control procedures, 3MBH02273025-02290677. See also above opinion on design history files.

[189] 3MBH00047382.

FDA cleared the Model 505 on June 17, 1996. The abstract and paper cited in the 510(k) were from 1991 and 1993. The earliest paper cited by Dr. David in his "Review of Literature Finding Risk from the Use of the Bair Hugger" starting on page 27 of his report is from 2002.

He states that "these papers do not provide sufficient clinical validation of the safety of the Bair Hugger 500 series in orthopedic implant surgical procedures, especially in the face of other published research which the Defendant has never provided to the FDA." He does not reference any publications prior to FDA clearance of the Model 505. Publications prior to 1996 providing clinical evidence supporting intraoperative thermoregulation include, for example, those published by Camus, Carli, Sessler, Hynson, Just, Kelley, Kurz, and Giesbrecht.[190]

The Quality System regulation defines design validation as follows:[191]

> *Design validation.* Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.

Even though FDA's design control requirements were not in place until 1997 and enforced by FDA until June 1998 as noted above, the 510(k) for the Model 505 included information on Augustine Medical's design control process as follows:[192]

[190] 3MBH01630160-01630195.

[191] 21 CFR §820.30(g).

> **Augustine Medical Design Control Process.** The design for the Bair Hugger® Model 505 Warming Unit was developed in accordance with Augustine Medical Design Control procedures. These procedures are in compliance with Good Manufacturing Practices as well as ISO 9000 standards.
>
> First, an input specification was written for this device based on market information and approved by our Product Development Advisory Board, as described in our design and development procedures. The final design was developed and evaluated by our Warming Unit product team, which comprises individuals from Marketing, Manufacturing, Manufacturing Engineering, Assembly Production, Purchasing, Regulatory Affairs, and Product Development.
>
> Failure Mode Effect and Analysis was performed during the prototype stage. (See Appendix H for more information.) This Unit was tested during the design development stage to ensure that the final design is safe and effective. Final validation testing was also performed on the final design (Appendix H).

The Model 505 510(k) includes safety tests, certifications, and results as noted in this report. The Design History File refers to clinical beta assessment of the devices. These tests, certifications, clinical papers and clinical beta assessments cited above meet the definition of "validation," both under simulation and actual use conditions according to the QS regulation.[193] Therefore, the Model 505 was properly validated, contrary to Dr. David's assertion.

9. On page 22 Dr. David states the engineers "quietly made the decision" to use the M20 media in the Model 750 after the June letter to FDA. The reference is an email from Karl Zgoda to the Cobra group.[194] Dr. David's referenced quote implies that Augustine Medical was required to report the change to FDA which it was not required to do according to regulations because the change is not of a reportable type listed in regulation and guidance.[195]

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[192] 3MBH00047282. See also my opinion on the Model 505 DHF.

[193] A product used in validations need not be the final designed product but the data should be applicable to the design characteristics of the final product.

[194] 3MBH00497304.

[195] 21 CFR Part 807 and FDA guidance on changes to 510(k) devices. To put device engineering changes in perspective there are about 3500 510(k)s submitted per year to FDA. However, there are 6500 medical device companies in the US alone per https://www.selectusa.gov/medical-technology-industry-united-states. Considering on average how many Class II non-exempt devices are made by these companies and foreign importers times a conservative estimate of average engineering changes per year per device I conclude that extremely few engineering changes for Class II non-exempt devices are considered by manufacturers to be significant changes per the 510(k) regulation.

Again Dr. David uses hyperbole to describe the comparison of efficiency between the M10 and M20 media based on an email from Porous Media.[196] The efficiency is less for the M20 compared to the M10 at the stated test conditions but Dr. David does not explain the note in the email that actual efficiency depends on design parameters of the filter. Also, he does not discuss the higher efficiencies against sizes that are also relevant to the operating room.

The test curve for a Model 750 filter that Dr. David reproduces in his report on page 23 shows increasing efficiency of a Model 750 filter up to 95% at 0.8 micron particle size.[197] The document does not describe the test method used by "camfil FARR" and how its method corresponds to the test methods used by Porous Media. Prior to this chart referenced by Dr. David in his report he had referred to a memo from Porous Media indicating a 58% efficiency at 0.3µM.[198] When shown Exhibit 173 Mr. Crowder from Pentair (formerly Porous Media) stated that the 58% efficiency at .3µm in the Porous Media email "...are lower values than was demonstrated by the data sheets from the media supplier."

Camfil's web site has information relevant to Dr. David's assertions regarding the Model 750 filter. Camfil designates MERV 14 filters and certain other non-HEPA filters as "High Efficiency" filters.[199] Mr. Crowder from Pentair testified:[200]

[196] 3MBH00022366.

[197] 3MBH00022367.

[198] Id.

[199] http://www.camfil.us/.

[200] Crowder deposition, 3/16/17, Page 16:7-18.

Q. Okay. If -- if I had, representing to the public, that I had a -- in this case a one-micron filter and it was removing 40 percent of the particles at that size, is it -- is it fair to call that a high-efficiency filter?

A. It could be.

Q. What does the term "highly efficient" mean to you?

A. I'm not aware of a technical definition for "highly efficient." I would, myself, interpret it to be media that's capable of removing very small particulates from airflow.

Therefore, according to these filter industry sources I must assume that Augustine company information stating that the Model 750 filter is "highly efficient" or some variation of that is legitimate.

Camfil provides the following information indicating legitimate use of MERV 14 filters in hospitals (the Bair Hugger filter is MERV 14) and particle sizes where the M20 media is highly efficient:

Air filters commonly applied in health care air conditioning systems have a very high efficiency on removing airborne droplet nuclei. The minimum standard of care for areas of a facility where infected individuals are cared for would have MERV 7 prefiltration and MERV 14 final filtration. Some of these areas would also have an additional stage of HEPA filters.

The initial efficiency of a MERV 14 filter on 1-5 micron size particles is well over 95%.

***

> Other contaminants, by general particle size range, include: bacteria—ranges from 0.30 to 4 microns; droplet nuclei—averages 3 microns; many allergens, fungi and bioaerosols—at least 3 microns; visible dust—10 microns; and a human hair—at least 80 microns in diameter.

10. On page 23 Dr. David refers to a 2003 email regarding a Bair Paws upgrade and Polar Air II.[201] The email states that the filtration level of the Model 505 must be matched by new devices or it must be proven that reduced filtration is safe. He does not disclose the preceding sentence that states, "Filtration of any kind is not required by regulatory standards, however it is expected by many customers. We currently offer sub-HEPA filtration that is the basis of safety claims in the 505's 510(k)." So, a plausible interpretation is that "sub-HEPA" filtration is needed for new devices. The Model 750 has sub-HEPA filtration with an M20 media.

11. On page 23-24, he refers to the letter-to-file and submission requirements for changes. He concludes that changes to the control mechanism, performance specifications, or materials are not being supplied to specifications, all raise new issues of safety and efficacy and require a new 510(k). In the case of the technological change of M10 vs. M20 media there is a change in material but Augustine Medical was the specifications developer and not Porous Media. The M20 media met Augustine Medical's new specification caused by the lack of future supply of M10 by Porous Media.

[201] 3MBH01031246.

FDA K97-1 guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" is not clear on the decision pathway when changing from M10 to M20 media.[202] FDA notes the following in the guidance:

> To be certain that a decision on when to submit a 510(k) is correct, one would probably need to enumerate all device types and all potential types of changes and then match each combination of device and change with a decision. Given that there are thousands of individual device types and possibly tens or hundreds of enumerable changes, this would be an impossible task. Furthermore, the resultant guidance would fill volumes, would probably be difficult to use, and would be unlikely to keep pace with an ever-changing technology.

There is more than one interpretation of the guidance on the need to submit a new 510(k) for the M10 to M20 change. One interpretation I have of the guidance flow charts is there is not a change of material type or formulation or supplier, as those decision points are described in the guidance, and no 510(k) is required. Another interpretation I have of the flow charts is there is a change in formulation and performance specifications of the material but indications are not changed and clinical data is not necessary, nor are there new issues of safety and effectiveness and again no 510(k) is required.

12. On page 24 Dr. David raises the issue of lack of validation of the 500 hour change in filter media. Dr. David does not assess the worst case conditions of use for filter efficiency, which is a new filter, or whether 500 hours of use can be adequately simulated. Mr. Zgoda testified as follows:[203]

> And I think the logic for me was that, you know, as filters get clogged they only get more efficient, they trap more particulate and so the interest would have been in is, you know, the filter so occluded that it affects the temperature

[202] FDA guidance K97-1, https://www fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080243.pdf.

[203] Zgoda deposition, 2/24/17, Page 148:25-149:6 and 149:24-150:10.

> Q. And then if we were to test a unit under the way Mr. Poppen's describing, we would have a better understanding of that issue, wouldn't we?...
> A. I guess I'm not sure I would agree with that because when you're -- if you want to run a unit for that amount of time, we have -- we would have a hard time recreating the environment used and actual facilities. So taking and putting it on a bench in a lab may not be indicative of what you would get in a a -- an account.

13. On page 24 Dr. David asserts the Model 750 was never tested or validated with respect to its effect on the operating room environment. I do not agree with this statement. It is my opinion that the safety aspects of the Model 750 questioned by Dr. David have been validated, in part, based on (1) publications including, for example, a government evaluation, (2) the independent evaluations by ECRI and The International Consensus Meeting on Periprosthetic Joint Infection in 2013, (3) the tested specifications of the M20 filter and its recommended use according to MERV standards, and (4) the clinical beta testing noted in the Design History File.

The 2010 letter to the editor by Memarzadeh at the National Institutes of Health concludes that FAW does not increase the risk of surgical site infection as follows:[204]

> NIH concludes that in both scenarios, there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection. Although squames from the anaesthesiologist location move upwards due to thermal plume and away from the surgical site, supply flows largely dictate airflow pattern. When the forced-air warmer is operating, the downward velocity from ceiling laminar diffuser is slightly less strong than when it is off. With same supply air temperature, the air temperature around the surgical table is warmer when the forced-air warmer is operating. Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff.
>
> This investigation validates Moretti *et al.*'s conclusion that forced-air warming technology does not increase the risk of surgical wound infection. Further, if the operating room ventilation system is designed properly, contaminating particles from staff around the patient will not impinge on the surgical wound due to 'thermal plume' dynamics.

[204] 3MBH01630506-01630507.

The consensus in the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infections report concludes that no studies have shown an increase in SSI related to FAW blankets as follows:[205]

Consensus: We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.

The 2013 ECRI Institute Report concludes evidence does not support discontinuance of FAW devices as follows:[206]

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

[205] 3MBH01630605.

[206] 3MBH01630611.

The ECRI report also notes the following:[207]

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

My prior comments include my assessment of the M20 filter testing, specifications, and MERV rating with applications in health care facilities. Ms. Danielson testified as follows:[208]

A. The current filtra -- filtration levels -- The current filter I'm aware has been reviewed in terms of filtration levels expected for sort of the -- the hospital standards for operating rooms. And again I'm not a technical expert, but the -- the current -- the capacity of the current filter is equivalent to the standard for hospital operating rooms.

And I think in terms of the purpose of the filter for the device, as I understand it, that that would -- it's -- there's filtered air in the OR to begin with. If the device filter is at the same level of filtration as air coming into the OR, I think it would be reasonable to -- to conclude that that's an adequate level of filtration for that device to -- to not disrupt or not contribute to contamination.

14. On page 25 Dr. David again alleges that the company "secretly" made changes to the Model 505 filter. In this report I have previously commented on his inaccurate characterizations. The change in filter for the Model 505 in 2009 did not require a new submission to FDA. I have

[207] Id.

[208] Danielson 3/17/17, 90:4-19.

also referred to testimony why the actual filtration level was not disclosed. Contrary to Dr. David's impression, the document to which he refers contains a lot of suggested information to provide to customers, including that the filter is sub-HEPA.[209]

On page 25 Dr. David states that the hazard analysis needs to be updated when there is a change in the device's components and refers to the change requirements in the Quality System regulation, although he misstates the regulatory cite. The Standard Operating Procedures for Arizant included a Post-Production Risk Analysis Procedure that was periodically updated.[210] The procedure provides for post-production reviews in two-year intervals that include the review of various subjects such as Engineering Change Orders (ECOs) and Process Change Orders (PCOs). The 2016/2017 FMEA for the Model 505 and 750 indicates the potential hazard of surgical site infection and related risk/benefit. I do not believe that the surgical site hazard was a new hazard at any point of marketing of a Bair Hugger and based on the risk/benefit information accumulated over time the estimate of risk remains as is now documented in the 2016/2017 analysis.

15. On page 25 Dr. David begins a discussion of a 2009 FDA inspection of Arizant. Dr. David notes that the Establishment Inspection Report states that "The warming unit has a 0.2µm HEPA filter" which it did not.[211] As I note above in this report there is no deposition testimony that Arizant intentionally mislead the FDA inspector.

[209] 3MBH00132832.

[210] 3MBH02290521-02290565.

[211] 3MBH00048067-00048085.

He also questions the specific literature provided to the FDA inspector that is referenced in the EIR. Mr. Westlin testified that he supplied the literature that responded to the FDA inspector's request as follows:[212]

A. I'd have to look here and see if they were, but I don't remember they were. But the discussion was the allegations that they were dealing with and the discussion was about what evidence we had otherwise, and that's why we presented the evidence that we had that there was not a concern.

***

Q. Okay. Now when you provided that literature that's listed here in the report, you would agree with me that that literature does not represent a fair totality of the literature on this issue of airborne contamination.

MR. SMITH: Objection to form.

MS. GARCIA: Join.

A. That's correct, but that's not what was asked for.

Dr. David refers to the inspector's statement on the lack of a procedure on environmental and contamination controls specific to microbial contamination. The EIR is unclear if there were no environmental and contamination control procedures whatsoever. In any case, the EIR does not include an observation pertaining to lack of environmental or contamination controls.

16. On page 26 Dr. David discusses what I call the nonsterile state of the Bair Hugger. Augustine Medical, Arizant and 3M never claimed in any labeling or advertising that any model of the Bair Hugger was sterile.[213] I am unaware of any warming device with a sterile labeling claim.

[212] Westlin deposition, 12/16/16, Page 143:3-8 and 144:6-14.

[213] Sterility is the absence of viable organisms.

So-called noncritical device surfaces, like those of the Bair Huggers, are recommended by FDA and CDC to be cleaned.[214] Dr. David notes that Bair Hugger instructions provide for external surface cleaning of the device. I am unaware of any electro-mechanical device placed outside the sterile field in an operating room with internal fan components to have sterilization or disinfection procedures for both external and internal surfaces.

17. On page 27 of his report Dr. David begins a section entitled "Review of Literature Finding Risk from the Use of the Bair Hugger." This section includes reference to 11 publications and two poster presentations. He states that "While the individual results of these studies are not definitive, collectively they support the conclusion that the Bair Hugger has the potential to cause surgical site infections in orthopedic surgeries."

Dr. David is a member of an FDA advisory committee. As such he should be aware of and consider the regulatory criteria by which FDA assesses data concerning the safety and effectiveness of medical devices for purposes of classification, clearance and approval. Criteria provided for the fair evaluation of all available evidence to render a decision on safety and effectiveness as follows:[215]

> "After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a

[214] FDA Disinfection and Sterilization Guidance, https://www fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf and https://www.cdc.gov/hai/pdfs/disinfection_nov_2008.pdf.

[215] 21 CFR §§860.7(c)(1) and (c)(2).

whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use."

***

Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

Dr. David's analysis does not meet these criteria. He references only 13 publications and posters. In comparison, for example, the April 2013 ECRI analysis I reference above in this report began with an unbiased examination of 180 studies. ECRI's report details its analysis of four publications that Dr. David does not reference.[216]

It is my conclusion that Dr. David's assessment is not fair in that it does not render a conclusion based on analysis of the data as a whole by FDA's criteria.

18. On page 31 Dr. David begins a section entitled "Defendant's Refusal to Mitigate Patient Risk." He discusses "Project Ducky" and the evaluation of a silver coating on the interior of the hose.

He refers to a quote by Dr. Michelle Hulse-Stevens concerning a consensus meeting but does not provide the opinion of that consensus conference which stated:[217]

[216] Papers by Huang, Moretti, Melling, and McGovern.

[217] 3MBH01630605.

Consensus: We recognize the theoretical risk posed by FAW blankets and that no studies have shown an increase in SSI related to the use of these devices. We recommend further study but no change to current practice.

He notes a quote from a document relating to the cost of a HEPA filter but does not include the entire quote in the same document that states the current filter is effective, as follows:[218]

Sorry also for the delay. Our filter description is a "high efficiency, 0.2 micron filter". It does not carry the HEPA designation. This is principally due to the added cost. We have studied this, as well as others in independent studies that have found that our current level of filtration is very effective.

I discuss Project Ducky and the antimicrobial coating in a prior opinion. Dr. David describes a 3M document on Blower Hose Ideation that does not comport with any notion that 3M/Arizant was unresponsive to customer input.[219] Rather, the ideations and other activities are indicative of Arizant's active design process taking into account customer input and competing designs. The ideations depicted in the drawings Dr. David displays were in response to marketing factors, not patient risk. . Winston Tan, a manager in the engineering group, testified as follows regarding the ideations:[220]

Q. Can you kind of describe what this document is for me.

A. Sure. In 2014 we were at the beginning stages of developing a new warming unit, and these were exploratory, some ideas, if we wanted to use some of the ideas on the new warming unit.

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[218] 3MBH00024682.

[219] 3MBH00630074.

[220] Winston Tan deposition, 3/10/17, Pages 104:12-17 and 105:1-7.

Q. Why was it important to keep the hose clean?
A. Just for the competitive landscape. We had some competitors out there that had a covering over the hose, and we were -- we were just looking at, when we did work on a new warming unit, these were some ideas that if --
These are features, competitive features.

Since what is represented by the ideation drawings are concepts at the very earliest stages, it is far from established that any of these concepts would be practicable and could be implemented.

In Section 8 Dr. David discusses his opinions regarding alternative devices. FDA has found other device technologies substantially equivalent, but FDA's findings do not render the other devices safer and FDA continues to permit the Bair Huggers to be marketed.

Dr. David speculates that the VitaHeat, Tableguard and Mistral-Air devices are safer. It is interesting that Dr. David does not identify the Augustine Medical Hot Dog as a safer device. These devices may have some different features compared to the Bair Hugger devices but different features present new hazards as is the case with the complaints for the Hot Dog device I discuss in this report..

I believe conclusions on comparative safety must be based on a complete comparative analysis of risks and benefits, complaints, all the relevant literature, independent third-party assessments, and the FDA recall and MAUDE databases to name a few sources of information.

VIII. SUMMARY REBUTTAL OF DR. DAVID'S LEGAL CONCLUSIONS AND RESPONSE TO PLAINTIFFS APRIL 2017 CONCLUSIONS

Summary Rebuttal of Dr. David's Legal Conclusions

Dr. David states that the Bair Hugger devices are not safe and adequately labeled, 3M/ Arizant did not meet good manufacturing practices and postmarket surveillance requirements, and the device is an unreasonable danger in the orthopedic operating rooms (Summary, Page 42-44). These allegations relate to violations of the prohibited acts of adulteration and misbranding.[221]

For eight years, from 2003 until 2011, I was the most responsible person in the FDA Center for Devices and Radiological Health for determining whether a medical device violated the laws and regulations FDA administers. I evaluated the evidence to determine whether the evidence supported bringing charges in the form of Warning Letters or enforcement actions. If I found the evidence insufficient I had the responsibility and authority to reject any or all advisory or enforcement actions.

The finding of a violation of the Act or regulations is ultimately a conclusion affirmed by a court. So-called FDA Warning Letters are advisory actions that are not final agency actions and FDA cannot be sued on their content.[222] Opinions of violations expressed in reports such as Dr. David's are not subject to the same legal scrutiny and due process occurring in the regulatory space.

In my opinion there is lack of evidence produced in Dr. David's report to support his assertion that the company acted in violation of the Act pertaining to the Bair Hugger, and that the Bair Hugger is adulterated or misbranded, as those prohibited acts and conditions are defined

[221] 21 USC Section 331.

[222] See FDA Regulatory Procedures Manual.

and described in Sections 331 (as well as 351 and 352) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.).

All the Bair Hugger devices were either cleared by FDA or are minor modifications of cleared devices. FDA's order finding these devices to be substantially equivalent provides reasonable assurance that they are safe and effective unless and until FDA considers them adulterated or misbranded.

There is lack of evidence produced in Dr. David's report that the Bair Hugger was adulterated under Section 351(h) of the Act pertaining to the Quality System (aka GMP) regulation as Dr. David claims. I refute his specific assertions in my report and detail, for example, the company's compliant design, complaint handling and reporting activities. FDA has inspected the company facilities multiple times, including for reasons related to Dr. David's assertions, the last time in late 2016, and has never taken an enforcement action against the company (i.e., Arizant or 3M, or the devices known as models of the Bair Hugger.[223] The company corrected to FDA's satisfaction all observations made during inspections and in Warning Letters.

As I have opined in this report the labeling for the Bair Hugger is not misbranded as Dr. David claims. FDA has never documented an observation in an inspection stating the labeling is deficient. All 510(k)s included labeling that was evaluated by FDA.

None of the literature evaluated by Dr. David attests to even one surgical site infection (SSI) that has been confirmed as caused by the Bair Hugger Model 750 or to any other Bair Hugger devices.[224] Prior to recent litigation there were few complaints submitted to FDA for

[223] Past Audit Documents 3MBH015157606-01789042. The Quality System regulation encompasses issues discussed by Dr. David, for example, complaint handling, corrective and preventive action, verification and validation and design control.

[224] Publications from 1987-2016.

Bair Hugger devices. FDA investigated Arizant's reporting procedures and decisions during inspections.

I have refuted his allegations regarding the filter used in the Model 505 and 750 and the company's transparency with FDA regarding the filter.

In a report published in April 2013 an independent test organization, ECRI, published its review of forced air warming and SSIs.[225] Their conclusions are supportive of the Bair Hugger devices and state as follows:

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

[225] Health Devices, April 2013, ECRI.

In sum, it is my opinion that the devices collectively known as the Bair Hugger meet the statutory and regulatory standard of reasonably safe and effective devices. Furthermore, they meet all relevant industry safety standards as evidenced by their verifications and validations and repeated certifications to safety standards by independent test laboratories.

Summary Statement Regarding Plaintiffs' Conclusions of April 2017

Plaintiffs have presented a list of conclusions in a motion filed on April 21, 2017. My report addresses the conclusions as follows:

1. 3M/Arizant conducted safety testing for the Bair Hugger as I describe in my analysis of the Bair Hugger 510(k)s and other comments regarding device testing. The devices were properly validated.

2. 3M/Arizant modified the efficiency of the Bair Hugger Model 750 based on performance requirements but still keeping the filter at an efficiency level consistent with hospital industry standards as I describe in my report. The company did not hide the filter specifications for the Bair Hugger Models 505 or 750 from FDA.

3. The Bair Hugger is a nonsterile device and therefore its surfaces are not free from potentially viable microorganisms. 3M/Arizant makes no claim that the Bair Hugger is sterile. All other warming devices with or without HEPA filters also cannot claim their devices to be sterile.

4. 3M/Arizant evaluated design changes to the Bair Hugger to respond to customer inputs as I describe in my report, and the company did not adopt the changes I describe in this report for valid scientific reasons.

5. 3M/Arizant has not disregarded complaints regarding its devices as I describe in this report. I defer in-depth analysis of tests, research and the literature to other Defendant experts.

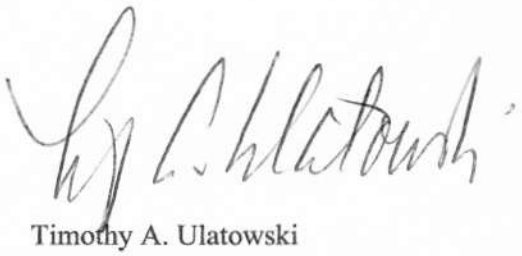
6. 3M/Arizant has communicated its assessment of the literature relevant to the issues in this litigation to FDA. An independent organization assessed all the relevant literature as I describe in this report. Plaintiff's expert I rebut assessed limited, selected literature in a comparably less than fair and thorough manner.

7. I defer to other witnesses on the Plaintiff's conclusion regarding manipulation of certain research.

8. I defer to other witnesses on the Plaintiff's conclusion regarding suppression of testing.

9. Defendant produced compliant labeling according to federal statute and regulations. All labeling for the Bair Hugger was examined by FDA multiple times in a succession of premarket submissions. The labeling includes instructions for use information as required.

I may supplement my report based on new information produced in this litigation.



Timothy A. Ulatowski

Dated: June 2, 2017

EXHIBIT 4

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

Information about the Use of Forced Air Thermal Regulating Systems - Letter to Health Care Providers

August 30, 2017

Dear Health Care Provider,

The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.

The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.

Therefore, the FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted. Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process.

Forced air thermal regulating systems, also called forced air warmers or forced air warming systems, are devices used to regulate a patient's temperature during surgical procedures. Forced air thermal regulating systems use an electrical blower to circulate filtered, temperature controlled air through a hose into a blanket placed over or under a patient.

To determine if there is an increased risk of surgical site infection when forced air thermal regulating systems are used during surgery, the FDA collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements

As always, please follow the manufacturer's instructions for use in the operating room/and or the post-operative environment.

FDA ACTIONS

The FDA will continue to actively monitor this situation and will update this communication if significant new information becomes available.

CONTACT US

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mail-to:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

Sincerely,
/s/
William Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in Letters to Health Care Providers (/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm)

EXHIBIT 5

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

health. DEVICES

EDITORS' NOTE

Augustine Temperature Management recently published press releases, e-mail blasts, and blog entries on this article, which appeared in the April 2013 issue of ECRI Institute's *Health Devices* journal and is titled "Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice."

ECRI Institute states that it did not participate in or approve of the above-mentioned materials, and warns that they should not be construed as representing our opinion or judgment.

Our views on forced-air warming are explained in our article, and we recommend that readers go here—and nowhere else—to learn what we think.

ECRI Institute
The Discipline of Science. The Integrity of Independence.

guidance ARTICLE

FORCED-AIR WARMING AND SURGICAL SITE INFECTIONS

Our Review Finds Insufficient Evidence to Support Changes in Current Practice

Maintaining normothermia during surgery is an important measure in preventing surgical site infections (SSIs). Several technologies are available to accomplish this during surgery, including the popular method of forced-air warming (FAW). Recently, however, some member hospitals have asked us about FAW and whether it might actually contribute to SSIs. Specifically, their questions were focused on whether the use of FAW during surgery (including orthopedic implant surgery) leads to an increased rate of SSIs as compared to the use of other methods of patient warming and, if so, whether such concerns merited discontinuing the use of FAW during surgery. In response to these questions, ECRI Institute has conducted an assessment of the published literature to determine whether the evidence supports a decision not to use FAW.

Based on our assessment, we do not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. This article explains our reason for this judgment.

THE IMPORTANCE OF MAINTAINING NORMOTHERMIA DURING SURGERY

Maintaining normothermia in surgery patients has been reported to significantly lower the risk of postoperative surgical wound infections (Kurz et al. 1996, Melling et al. 2001). Hypothermia triggers vasoconstriction, ultimately resulting in a reduction of the partial pressure of oxygen in tissue. This in turn impairs the body's ability both to fight infection at the wound site and to promote wound healing. Maintenance of body temperature during and after surgery is recommended in practice guidelines by a variety of organizations, including the Centers for Disease Control and Prevention, Guideline for Prevention of Surgical Site Infection, 1999; the American Society of Anesthesiologists, Practice Guidelines for Postanesthetic Care, 2002; the American College of Cardiology/American Heart Association, ACC/AHA 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery, 2007; and the National Collaborating Centre for Nursing and Supportive Care, The Management of Inadvertent Perioperative Hypothermia in Adults, 2008.

FORCED-AIR WARMING MAY DISTURB AIR PATTERNS IN THE OPERATING ROOM

FAW is a popular method to maintain normothermia during surgery. FAW systems (warming units and blankets) are designed to warm patients by gently blowing warm air onto the skin of the patient via an air blanket. But there are other methods to warm patients during surgery, such as conductive-fabric warmers and water-circulating warmers. The theoretical concern raised with the use of FAW is that air currents created by the system may carry microbes that might contaminate the surgical site.

Some studies have investigated this concern, looking at the impact of FAW on laminar airflow systems—especially the potential disruption of the downward airflow patterns. For example, five studies (Belani et al. 2012, Dasari et al. 2012, Legg et al. 2012, Legg and Hamer 2013, McGovern et al. 2011) demonstrate that the exhaust from FAW units results in thermal currents that rise into the downward ventilation airflow of the laminar airflow systems studied. The disruption of airflow patterns is particularly worrisome in laminar-flow and ultraclean ORs, in which a wide variety of implant surgeries are performed. The argument is that mobilization of contaminated air near the floor or decreased effectiveness of the downward laminar airflow pattern could contribute to an increased rate of SSIs, including prosthetic joint infections (PJIs), compared to when other methods of patient warming are used. This is especially concerning during orthopedic surgeries because contamination of the surgical site may present a greater risk of developing a PJI, which is

UMDNS terms. Warming Units, Patient [17-570] ■ Warming Units, Patient, Circulating-Fluid [17-648] ■ Warming Units, Patient, Conductive Layer [25-785] ■ Warming Units, Patient, Forced-Air [17-950] ■ Warming Units, Patient, Radiant [13-248] ■ Warming Units, Patient, Radiant, Adult [13-249]

harder to treat and resolve than would be the case with SSIs in general. These studies, however, only raise questions about airflow disruptions. Demonstrating that airflow patterns change when FAW is used does not establish that it results in increased bacterial contamination or increased rates of SSI and PJI as compared to use of other methods of patient warming.

WHAT THE EVIDENCE SHOWS

The literature review process we used involves articulating a specific question to answer, creating search strategies for a comprehensive and objective literature search, and identifying inclusion and exclusion criteria that are applied to each study. The studies that meet the inclusion criteria are evaluated for their design and the potential for study bias—specifically, study features that could impact whether the treatment being studied is responsible for the outcomes observed. Studies are then analyzed for the information they contain.

The question we asked was: Do surgical patients whose body temperatures were controlled with FAW systems (when used as intended) have an increased risk of SSIs compared to patients whose body temperatures were controlled by another method? Our inclusion criteria required that the study include a comparison of SSI rates and that it have at least two arms (FAW compared to at least one alternative warming technology), with a minimum of 10 patients (per arm) undergoing surgery. We also required that studies include documentation of body temperature maintenance for all methods and that they report all infections that occurred within a follow-up period of at least 30 days. (Our complete inclusion criteria and the reasoning behind them can be found in "Study Inclusion Criteria" on this page.)

Our search of the published literature identified over 180 studies potentially related to our question. These studies were all eliminated for a variety of reasons. Any study that was not clinical in nature—that is, that did not involve human surgical patients—was excluded. We also eliminated studies that looked at OR contamination when FAW units were used but did not examine SSIs. Granted, some of these studies report increased microbial contamination within FAW units (e.g., Albrecht et al. 2011) or increased particle counts (particles injected into the air, not bacteria) at monitored OR locations when FAW units were being used (Legg et al. 2012, Legg and Hamer 2013). But while studies like these raise questions, they don't establish that an increased risk of SSI exists with FAW compared to other warming technologies. For similar reasons, we excluded studies that solely examined air current patterns that may affect the distribution of microbes.

While we did not find any studies that met all our inclusion criteria, we did identify four studies that came close to meeting our criteria and that examined SSI rates following clinical procedures:

- Two studies—one by Huang et al. (2003) and one by Moretti et al. (2009)—primarily involved assessment of bacterial counts in different locations of the OR and at the surgical wound edges. These studies used slightly different approaches: Huang did cultures at the start and finish of surgery with use of an Augustine Medical Bair Hugger FAW system; Moretti did cultures with and without use of the Bair Hugger FAW system. The authors of the studies reported that no SSIs occurred in any patient in the studies (total of 46 patients combined). *Reason for exclusion:* These studies lacked a comparison of FAW to an alternative warming system.
- A study by Melling et al. (2001) looked at SSI rates in a total of 421 patients who underwent breast, varicose vein, or hernia surgeries. Patients were randomized into three groups: 138 patients with localized warming before surgery, 139 patients with whole-body FAW before surgery, and 139 patients with no warming before surgery

STUDY INCLUSION CRITERIA

The following are the inclusion criteria we used when determining which studies would be included in our analysis. These criteria were developed before the clinical literature review.

- Studies must have enrolled human subjects who underwent surgery involving the creation of a surgical wound. Studies without human subjects do not provide generalizable conclusions.
- Studies must evaluate a forced-air warming system and at least one other means of maintaining a patient's body temperature (with devices used as intended) during surgery. Such comparison studies are needed to determine the extent to which the FAW system is responsible for altering the infection risk compared to other means of maintaining a patient's body temperature, while all other factors in promoting or reducing infection risk are held constant.
- Studies must have data showing that the body temperature of the patient was maintained by both the FAW system and the comparison technology. If the comparison technology or the FAW system was not effective at maintaining body temperature, then this failure rather than other technology differences may be responsible for any differences in infection rate.
- Studies must be randomized controlled trials or nonrandomized comparison studies with at least two treatment arms.
- Studies must have at least 10 patients enrolled per study arm.
- Studies must report the number or rate of surgical site wound infections within 30 days of the surgery.
- Studies must be published in English.
- Studies must be published as full articles in a peer-reviewed journal.

LAWSUIT ALLEGES CONTAMINATION BY FORCED-AIR WARMER

ECRI Institute has learned that in March 2013, a lawsuit was filed against 3M Corporation alleging that a patient sustained a periprosthetic infection while undergoing hip replacement surgery as a result of contaminants being deposited in the surgical site by a 3M Bair Hugger forced-air warmer.

We have reviewed the plaintiff's petition. It does not present any new information that would alter the conclusions we have drawn in this article based on our review of the published literature.

Case information can be found in the press release from the plaintiff's attorneys at www.prweb.com/releases/2013/3/prweb10554160.htm.

(control group). This study compared the Augustine Medical Bair Hugger FAW system to the Augustine Medical Warm-Up. The Warm-Up (which is no longer available for purchase) was a noncontact normothermic wound therapy system designed to provide warmth and humidity in the wound area and was therefore not intended to maintain a patient's body temperature during surgery. The patient warming occurred for a minimum of 30 minutes before surgery. The SSI rate was not significantly different between warming systems (3.6% for Warm-Up, 5.8% for Bair Hugger, $p = 0.4$), but was significantly lower in warmed patients (5%) versus nonwarmed (14%, $p = 0.001$). *Reason for exclusion:* There was no comparison of whole-body warming methods used during surgery to maintain normothermia.

- A study by McGovern et al. (2011) that examined effects of warming devices on OR ventilation also provided data on PJIs in patients treated by different technologies for maintaining body temperature during surgery. The study reports on 1,437 patients who underwent joint replacement surgery; 1,066 patients had surgery during a period when the hospital used FAW, and 371 had surgery during a period when the hospital switched to using conductive fabric for warming. Data was collected retrospectively. The study reported PJI rates of 3.1% for FAW versus 0.8% for conductive-fabric warming, which was a significant difference ($p = 0.024$, Wald test) when data was combined for hip and knee surgeries. Based on the study's findings, the authors recommend that FAW not be used in orthopedic surgeries. *Reasons for exclusion:* This study lacked documentation of normothermia during surgery. In addition, the authors reported that both the prophylactic antibiotic regimen and thromboprophylaxis regimens were altered during the study period. Since the two types of warming treatment were not applied concurrently, other treatment differences or changes during the two different time periods may have influenced PJI rates. Other notable limitations of the study are that data was collected retrospectively rather than from a prospective study; the data was from only one hospital; and the authors did not state whether the data was collected from all patients who underwent primary hip and knee replacement surgery during the reported time periods.

  Note that no information was provided on what model warming devices were used on patients in the SSI portion of the study, only whether the devices were conductive fabric or FAW. However, in the operating-theater-ventilation portion of the study, a Bair Hugger warming unit with a Model 540 FAW blanket and a Hot Dog brand Model B110 conductive-fabric blanket were used.

CONCLUSIONS

Based on our focused systematic review of the published literature, we believe that there is insufficient evidence to establish that the use of FAW systems leads to an increase in SSIs compared to other warming methods. Although one study (McGovern et al.) presents data that suggests higher PJI rates with use of FAW compared to an alternative warming method, this study has serious limitations such that its findings on PJI rates cannot be considered conclusive. Studies that look at FAW's contribution to OR air contamination and/or airflow disruption raise questions about the technology and its potential impact, but they do not provide sufficient evidence to demonstrate that the use of FAW poses a greater risk of SSIs or PJIs than the use of other warming methods.

Consequently, ECRI Institute does not believe that the currently available evidence justifies discontinuing the use of FAW during surgery. We will continue to monitor this topic through the published literature and will update our recommendation as warranted.

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Legg AJ, Hamer AJ. Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J* 2013 Mar;95-B(3):407-10.

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Moretti B, Larocca AM, Napoli C, et al. Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection? *J Hosp Infect* 2009 Sep;73(1):58-63.

National Collaborating Centre for Nursing and Supportive Care. Inadvertent perioperative hypothermia: the management of inadvertent perioperative hypothermia in adults. Clinical guideline; no. 65. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Apr. Also available: http://guidance.nice.org.uk/CG65.

This report appears in the April 2013 issue of ECRI Institute's monthly Health Devices journal, which is provided to members of ECRI Institute's Health Devices System, Health Devices Gold, and SELECTplus™ programs. Health Devices features comparative, brand-name evaluations of medical devices and systems based on extensive laboratory testing and clinical studies. ECRI Institute's evaluations focus on the safety, performance, efficacy, and human factors design of specific medical devices and technologies.

For questions about ECRI Institute's membership programs, contact us by telephone at (610) 825-6000, ext. 5891; by e-mail at clientservices@ecri.org, or by mail at 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA.

Contact ECRI Institute's European office at info@ecri.org.uk; ECRI Institute's Asia-Pacific office at asiapacific@ecri.org; and ECRI Institute's Middle Eastern office at middleeast@ecri.org.

EXHIBIT 6

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

Report of Dr. Yadin David
Tommy Walton v. 3M & Arizant Healthcare

September 28, 2015

A. Background and Qualifications.

I have been a biomedical engineer for over 30 years. I completed my academic training at the bachelor (B.Sc., Electrical Engineering, 1972), masters (M.Sc., Electrical Engineering, 1973), and doctorate (Ed.D., 1983) levels at West Virginia University ("WVU"). I am currently a Principal at Biomedical Engineering Consultants, LLC in Houston Texas. I held academic appointment of adjunct Assistant Professor at Baylor College of Medicine from 1987–2010, and I have been adjunct Assistant Professor at the University of Texas, School of Public Health since 2008. I am presently a registered Professional Engineer (P.E.) in Texas and also certified in Clinical Engineering (C.C.E.) by the International Certification Commission as well as by the Healthcare Technology Commission. I have been awarded the FDA Commissioner's Special Citation, the American College of Clinical Engineering ("ACCE") Lifetime Achievement Award, the ACCE/Association for Advancement of Medical Instrumentation 2008 Humanitarian Award, and the WVU Distinguished Professional Achievement and Service award.

In my professional capacity, I am a member of the Advisory Panel of the U.S. Food and Drug Administration ("FDA"). I was re-appointed to the Advisory Panel on December 31, 2013. In addition, I also serve as Chairman of the FDA's Device Good Manufacturing Practice Advisory Committee. As member of the panels, I advise members of the FDA staff about issues related to applications submitted to the FDA for the 510(k) review process, device labeling, and special controls. Additionally, I founded and served as president of the Healthcare Technology Foundation, am currently the chairman of the Health Technology Training Group of the

EXHIBIT B

International Union for Physical and Engineering Sciences in Medicine, am a Fellow of the ACCE and of the American Institute of Medical and Biological Engineering societies, and serve on the board of the Clinical Engineering Division of the International Federation of Medical and Biological Engineering.

I first became familiar working with medical devices, and electro-medical devices in particular, while I was an orderly in the operating rooms at WVU. Later, as a research assistant in the Department of Anesthesiology at the WVU School of Medicine, I worked with a wide variety of medical equipment including cardiac stimulators, thermos regulating devices used in regulating patient's temperature in areas such as the surgical theater as well as of new born babies in the neonatal intensive care units, among other equipment. Through my academic affiliations at the Department of Anesthesia at the medical school at the West Virginia University and the Department of Pediatrics at the Baylor College of Medicine, I have participated in several clinical investigations of other types of electrical medical equipment, such as equipment measuring brain electrical stimulation, electromagnetic compatibility monitoring, telemedicine quality, blood pressure response to electrical stimulation, post cardiac surgery patient temperature changes, and brain blood flow studies. The results of many of these investigations were published in peer-reviewed medical periodicals and journals.

I also engage with manufacturers of medical devices and supplies, hospitals, and medical equipment vendors to analyze process improvements and work flow as each relates to medical technology. In this capacity, I visited design engineering and manufacturing facilities and plants of General Electric, Drager, Siemens, Mind ray, and Cardinal Health (IMED/Alaris). In that regard, I have had specific discussions regarding electro-medical features and improvements and future product releases. In addition, I have served as engineering consultant for start-up

companies that bring new products to the market. My responsibilities have generally included validating the engineering aspects of the devices and, on at least one occasion, assisting in the preparation of a 510(K) Premarket Notification.

While at Texas Children's Hospital, I served as chairman of the Medical Technology Evaluation Committee, which was responsible for evaluating technologies deployed at the point-of-care. As part of my work in this capacity and other evaluative capacities, I have used peer-reviewed scientific studies to support and facilitate the evaluation and deployment decisions of various types of medical technology. For instance, I was involved with the selection of a new imaging system at Texas Children's Hospital for cardiac examination of pediatric patients. The selection process involved reviewing the product, conducting clinical testing, and considering the evidence gathered and the conclusions reached in peer-reviewed scientific publications that documented radiation dose conditions and the resulting image quality produced in a similar population. Likewise, I took similar steps in the process of equipment selection for drug administration equipment, including, among other things, reviewing manufacturer's provided literature.

I have served as an expert in previous litigation involving medical products including surgical instruments, infusion pumps, thermos regulating devices, and rehabilitation products (skin warmers, chairs, and their supplies) and patent infringements. My services are charged at a rate of $400 per hour except for deposition and court testimony where the rate is $450 per hour. A copy of my Curriculum Vitae is attached here (Appendix A).

B. Materials Reviewed

In connection with my work in this case, I have reviewed the following materials:

3M Document Production (*by Bates Number*)

3M00004714	3M00048950
3M00012227	3M00044661
3M00011714	3M00050246
3M00047186	3M00018346
3M00011841	3M00050890
3M00018978	3M00048971
3M00004510	3M00038453
3M00044704	3M00048972
3M00011946	3M00006130
3M00047521	3M00020056
3M00043448	3M00075491
3M00050507	3M00051524
3M00019076	3M00006007
3M00048757	3M00006044
3M00016161	3M00075426
3M00004460	3M00009517
3M00007318	3M00036371
3M00037587	3M00009556
3M00004534	3M00007956
3M00036746	3M00041013
3M00004615	3M00017053
3M00036759	3M00006354
3M00017385	3M00017056
3M00019903	3M00048911
3M00004611	3M00006295
3M00007520	3M00017165
3M00048973	3M00006352
3M00019934	3M00018949
3M00011528	3M00018953
3M00011536	3M00038988
3M00048928	3M00004540
3M00047087	3M00050683
3M00044642	3M00075491

Depositions

David Westlin
Karl Zgoda
John Rock
Troy Bergstrom
Gary Hansen
Al Van Duren
Teryl Woodwick-Sides

Scientific Literature

Leaper, Albrecht, Gauthier. *Forced air warming: a source of airborne contamination in the operating room?* Orthopedic Review, October 17, 2009.

Gjolaj, Ahlbrand, Yamount, Armstrong, Brock-Utne. *Don't Forget to Change the Bair Hugger Filter.* ASA Presentation, October 20, 2009.

Leaper, Albrecht. *"Forced-air warming blowers: an evaluation of filtration adequacy and airborne contamination emissions in the operating room."* American Journal of Infection Control, May 2010.

McGovern, Albrecht, Belani, Nachtsheim, Partington, Carluke, Reed. *"Forced-air warming and ultra clean ventilation do not mix."* The Journal of Bone and Joint Surgery, July 2011.

Legg, Cannon, Hamer. *Do forced air patient warming devices disrupt unidirectional downward airflow?* The Journal of Bone and Joint Surgery, September 2011.

Dasari, Albrecht, Harper. *Effect of forced air warming on the performance of operating theratre laminar flow ventilation.* Anesthesia, October 2011.

Legg, Hamer. *Forced-air patient warming blankets disrupt unidirectional airflow.* The Journal of Bone and Joint Surgery, November 2012.

Belani, Albrecht, McGovern, Reed, Nachtsheim. *Patient Warming Excess Heat: The Effects of Orthopedic Operating Room Ventilation Performance.* Anesthesia & Analgesia, August 2013.

Reed, Kimsberger, McGovern, Albrecht. *Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne contamination emissions.* AANA Journal, August 2013.

Wood, Moss, Keenan, Reed, Leaper. *Infection control hazards associated with the use of forced air warming in operating theatres.* Journal of Hospital Infection, July 2014.

Other Materials

ECRI Report on Forced Air Warming
International Consensus Meeting on Periprosthetic Joint Infection
Doctor Says a Device He Invested Poses Risk, New York Times, Dec. 24, 2010
FDA Establishment Inspection Report (EIR), Nov. 17, 2010
Reference Materials from FDA Website

I expect to review additional materials as they become available, as well as additional deposition testimony which may be taken in this case. As such, I reserve the right to supplement or otherwise to modify my opinions in this case.

C. Overview of Medical Device Regulatory Process

This brief overview covers the FDA's authority to regulate medical devices, and the manufacturer's responsibility to comply with its applicable regulations. The FDA is the agency within the Department of Health and Human Services (HHS) responsible for regulating the safety and effectiveness of medical products and of the marketing material used by manufacturers including the statements in product labeling in the United States. The FDA regulatory enforcement powers are contained in the Federal Food, Drug, and Cosmetic Act (the "Act"), which is published in the Federal Register and codified in Title 21 of the Code of Federal Regulations (CFR) and official guidance publications posted by the agency.[1] Within the FDA, the Center for Devices and Radiological Health (CDRH) mission is to protect and promote the public health through in part the development and implementation of medical device regulations

[1] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.

and post-market surveillance. This center responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States.

However, to ensure the achievement of device's safety and effectiveness requires the cooperation of every stakeholder involved in the total life cycle management of a medical device's risks. That includes the manufacturer, FDA, distributors, and the end users. Independent agencies, such as the Institute of Medicine and the Government Accountability Office (GAO) have issued reports over the years that recognized the FDA lacks the capacity to provide adequate review and clearance oversight to the large volume of food, products, and drugs brought to the market. These findings further emphasize the FDA heavy dependence on medical product manufacturer compliance with its responsibilities as required in the premarket notification process and section 510(k) of the FD&C Act [21USC §360]. It is the manufacturer's responsibility to ensure its devices are safe, labeled and marketed in accordance with the cleared or approved indications for use.

Medical device manufacturers are required to establish compliance with the regulatory safeguards of the Act through registration and submission of a premarket notification -- a 510(k) clearance, or Premarket Approval -- if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. The 510(k) process is focused on equivalence measure to determine market clearance, on how substantially equivalent the newly intended marketed product is to a legally marketed pre-1976 device. This means the manufacturer represents that the new device is no more risky and no less effective than the

predicate device it is being compared to. A database of released 510(k) clearances can be searched by notification number, applicant, device name, or FDA product code.[2]

In addition, regulations require that manufacturers of medical devices distributed in the United States must also comply with other requirements, such as: establishment registration, medical device listing, premarket approval, quality system regulation, labeling requirements, and medical device reporting.[3]

It is prohibited under Section 301 of the Act for a manufacturer to sell a medical device in the United States that is not safe, effective and adequately labeled. 21 U.S.C. § 331. Specifically, Section 301 of the Act prohibits the following acts:

(a) The introduction or delivery for introduction into interstate commerce of any device that is adulterated or misbranded.
(b) The adulteration or misbranding of any device in interstate commerce.
(c) The receipt in interstate commerce of any device that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 505 or 564.

* * *

(g) The manufacture, within any Territory of any device that is adulterated or misbranded.
(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

* * *

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

* * *

[2] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
[3] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationand Guidance/Overview/default.htm#reg.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

* * *

(q) . . . (2) With respect to any device, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

* * *

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

* * *

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act [42 USC § 262(h)]; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

Of the early steps in its regulatory submission a manufacturer must take prior to marketing a device that fall under FDA jurisdiction is to identify risk classification class for their device, unless the product is intended only for export or its use will be very limited as a "custom device." This classification system is one of the corner stone of the device regulation process. The Congress established three classes of devices, based on the regulatory requirements needed to provide reasonable assurance of their safety and effectiveness. As such, the FDA classifies medical devices into one of three regulatory classes based on the level of risk associated with use of the device and the level of control necessary to reasonably assure that the device is safe and effective for its intended use. The three classes are: Class I, Class II, and Class III. Devices posing the lowest risk of injury or illness are placed in Class I and are subject to regulation through "general controls." Examples of Class I devices include elastic bandages and tongue depressors, present minimal potential for harm to the user. General Controls include provisions

for adulteration, misbranding, establishment registration and device listing, premarket notification [510(k)], records and reports, and Good Manufacturing Practices/Quality Systems Regulation (QSR), among others. Class II devices are potentially more harmful, pose incrementally greater risk such that the General Controls are not sufficient to provide reasonable assurance of safety and effectiveness. Therefore, Class II devices must comply, in addition to General Controls, also with "Special Controls." Special Controls may include labeling requirements, performance standards, guidelines, postmarket surveillance studies, or other controls the FDA deems necessary in order to provide reasonable assurance of the safety and effectiveness of the device. The Bair Hugger device, was cleared to market with the designation of a Class II devices. Electrocardiographs and powered bone drills are other examples of Class II medical devices. While class I and II devices are cleared by the FDA to market, class III devices are approved by the FDA to market.

The riskiest devices, such as some implants and life-supporting devices, are placed in Class III and generally are subject to premarket approval (PMA), which means that an application must be submitted to and approved by FDA before the device may be legally marketed. Class III devices are devices for which there is no sufficient information to place then in either Class I or II and present a potential unreasonable risk of injury or illness Before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" ("PMA" may refer to either premarket approval or premarket application) from FDA. To obtain a PMA, the manufacturer must submit information to FDA in a premarket approval application that provides reasonable assurance that the device is safe and effective for its intended use. Class

II and III present progressively more complex regulatory issues however Class III devices are subject to premarket controls in addition to general controls to ensure safety and effectiveness. After determining the class of the device intended to market, manufacturer can continue through one of two types of premarket review if they desire to legally marketed their device in the United States, unless exempt under FDA regulations. Class I and II devices subject to premarket review are only required to obtain FDA clearance through the premarket notification, or the 510(k) process, while Class III devices are required to obtain FDA approval through the more stringent PMA process. Most Class I devices and a few Class II devices are exempt from the 510(k) requirements but are not exempt from other General Controls, discussed above. All medical devices must be manufactured under a quality assurance program, Current Good Manufacturing Practice (cGMP), be suitable for the intended use, be adequately packaged and properly labeled, and have establishment registration and device listing forms on file with the FDA.

The clearance path under the 510(k) regulation presents notification application options. The Traditional method of demonstrating substantial equivalence, the Special 510(k) application, and the Abbreviated 510(k) application. This is part of the FDA effort to "increased reliance on postmarket controls to expedite premarket review" (section 513 of the Act, as amended by section 205 of the FDAMA).[4] The Special 510(k) is also known as "Device Modification" option. Under this option of the new FDA paradigm, a manufacturer who is intending to modify its own legally marketed device will conduct the risk analysis and the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the

[4] *See* http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm

design input requirements. Once the manufacturer has ensured the satisfactory completion of this process, a "Special 510(k): Device Modification" may be submitted."[5]

The Abbreviated 510(k) option, which relies on the use of guidance documents, special controls, and recognized standards to facilitate the 510(k) review. Therefore, device manufacturers may choose to submit an Abbreviated 510(k) when: (1) a guidance documents exists, (2) a special control has been established, or (3) FDA has recognized a relevant consensus standard. An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87. In addition, manufacturers submitting an Abbreviated 510(k) that relies on a guidance document and/or special control(s) should include a summary report that describes how the guidance document and/or special control(s) were used during device development and testing."[6] Manufacturers submitting an Abbreviated 510(k) that relies on a guidance document and/or special control(s) should include a summary report that describes how the guidance document and/or special control(s) were used during device development and testing.

In sum, a manufacturer seeking clearance for their new device must identify a legally marketed device, a predicate, to show substantial equivalency (SE) when pursuing the 510(k) clearance path to market. Such SE determination[7] means that the both devices have (1) the same intended use and the same technological characteristics as the predicate(s); or (2) the same intended use and different technological characteristics, but the difference does not raise

[5] The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance, FDA Guidance Documents, March 20, 1998

[6] The New 510(k) Paradigm Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Final Guidance, FDA Guidance Documents, March 20, 1998

[7] The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff, July 28, 2014.

questions related to the new device's safety and effectiveness, and the information submitted to FDA. This process relies heavily on the manufacturer to provide accurate information.

The manufacturer is also charged with the responsibility to ensure compliance with labeling regulations. Labeling regulations pertaining to medical devices are found in Parts 801 and 820 of Title 21 of the Code of Federal Regulations (CFR).[8] Section 502 of the Act says:

> A drug or device shall be deemed to be misbranded--
>
> > (a) False or misleading label. If its labeling is false or misleading in any particular.
> >
> > * * *
> >
> > (f) Directions for use and warnings on label. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.
> >
> > 21 U.S.C. § 352.

The regulations promulgated under the Act also state, in part:

[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/default.htm#link_2.

> *Adequate directions for use* means directions under which the layman can use a device safely and for the purposes for which it is intended. Section 801.4 defines *intended use.* Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:
>
> (a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.
> (b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.
> (c) Frequency of administration or application.
> (d) Duration of administration or application.
> (e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.
> (f) Route or method of administration or application.
> (g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.[9]

A device may not be marketed in the U.S. until the 510(k) applicant receives a letter (i.e., order) declaring the device substantially equivalent, thereby "clearing" the device for marketing. This is an important distinction in that the device is not technically "approved" by the FDA as with a PMA but instead is said to be cleared for marketing. The FDA uses the Least Burdensome Provision of the FDA Modernization Act of 1997: Concept and Principles, for evaluating and determining substantial equivalence. These principles act as a guide for the FDA to only request information that is necessary to making substantial equivalence determinations, where "necessary" means the minimum required information that would support a determination of

[9] 21 CFR 801.5; see also http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/ CFRSearch.cfm?CFRPart=801.

substantial equivalence between a new device and a predicate device.[10] The 510(k) process does not reflect an approval by the FDA of the device's safety.

D. Defendants' 510(k) Clearance and Subsequent Regulatory Interactions do not Establish the Safety of the Bair Hugger 750 in Orthopedic Implant Surgeries.

I reviewed the deposition of David Westlin, who is a regulatory affairs manager with 3M. Prior to the merger, Mr. Westlin was the chief compliance officer for Arizant Healthcare. According to Mr. Westlin, his duties included "supporting product regulations or registrations, assuring the products are built and designed according to the regulations, make sure the products are safe and effective."[11] Mr. Westlin was heavily involved the 510(k) submission for the Bair Hugger 750 as well as later interactions with the FDA.

Mr. Westlin states that in the safety summary section of the 510(k) submission, "…there were some clinical studies referenced demonstrating a -- that mitigation that was taken eliminated the potential for contamination as it was addressed in the summary – the FDA or the 510(k) summary."[12] A review of the 510(k) safety summary shows that these studies are:

> Hall, A. *Bair Hugger Warmer Does Not Increase Microbial Contamination in the Operating Room*.
>
> Zink, R.S. *Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room*.

The Hall reference was an abstract presented at a 1991 post-graduate assembly, and not available for review. It was not a published peer-reviewed study, and the details of the abstract or its applicability to this case cannot be determined. The 1993 Zink article concerns an extremely

[10] http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm284443.pdf
[11] Westlin Deposition, 6:7 to 6:10.
[12] Westlin Deposition, 10:22 to 11:2.

small test on eight healthy volunteers. Culture plates were placed on a single location on the abdomen. The test was not specific to orthopedic surgical procedures. These references provide no clinical validation of the safety of the Bair Hugger in orthopedic implant surgical procedures, especially in the face of other published research which was never provided to the FDA. Even Mr. Westlin acknowledges that these two references do not "represent the fair totality of clinical study on the Bair Hugger."[13] In connection with my work in this case, I have reviewed numerous peer-reviewed articles and scientific publications which indicate that the Bair Hugger can disrupt unidirectional airflow, introduce contaminates, and contribute to the increase of prosthetic joint infection.[14]

In the 510(k) submission for the Bair Hugger 750, Arizant stated the unit contained a HEPA filter. Mr. Westlin claims that "subsequent to the submission, we filed an addendum to the 510(k) informing FDA that we would be -- wanted to add the option to have the standard filter, the equivalent filter to what was in the model 505."[15] However, the "option" that Mr. Westlin described was actually a "replacement." Arizant never sold a single Bair Hugger 750 with a HEPA filter.[16] In fact, the reason that Arizant chose not to use a HEPA filter on the device was made "principally due to the added cost."[17]

In 2009, the Arizant Healthcare facility was subject to a FDA audit, chiefly aimed at addressing issues relating to the failure to report burn injuries. During this audit, the FDA engaged Mr. Westlin in discussions "about contamination concerns regarding the Bair Hugger

[13] Westlin Deposition, 138:7.
[14] *See* Section B, Materials Reviewed.
[15] Westlin Deposition, 36:7 to 36:11.
[16] Westlin Deposition, 38:3.
[17] 3M00018953.

temperature warming unit."[18] The FDA inspector noted that "the firm does not have a procedure concerning environmental and contamination controls specific to microbial contamination."[19] Moreover, during this inspection, the FDA was led to falsely believe that that "the warming unit has a 0.2 μm HEPA filter which is in place a secondary safeguard against contamination."[20] As discussed above, the unit does not actually have a HEPA filter.

During the FDA audit, Mr. Westlin provided the inspector with selected copies of studies which the company felt was favorable on the issue of forced air warming safety. However, Arizant once again neglected to provide the FDA a fair sample of the body of relevant literature, and it did not provide a single study from the large body of literature which has identified an infection hazard from Bair Hugger devices.

The FDA audit also made the important observation that "the only cleaning instructions provided with the units" concern exterior cleaning.[21] There are no instructions concerning internal decontamination. I have also reviewed an affidavit signed by five former product engineers of Arizant which states that "in our opinion, there is no practical way to clean and decontaminate the air-flow path of the forced air warming systems."[22]

However, Mr. Westlin dismissed the concern of internal contamination of Bair Hugger units during his deposition. Mr. Westlin claimed that Bair Hugger units "don't need to be decontaminated on the inside."[23] However, multiple studies have found internal contamination problems with Bair Hugger devices. For example, in a study published in the October 2009 issue

[18] 3M00075495.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] 3M00004540.
[23] Westlin Deposition, 64:14 to 64:15.

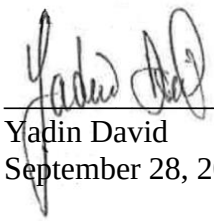
of Orthopedic Review, Leaper *et al* found that the Bair Hugger blower surfaces are contaminated.[24] That same month, a group of Stanford Medical School physicians presented the findings of a study on contamination to the American Society of Anesthesiologists. Their study discovered that the distal ends of the 12 out of 29 tested Bair Hugger devices were positive for pathological growth.[25] The Stanford group noted that "it has been recommended that an additional microbial filter be fitted to the distal end of the BH hose."[26] My review of testimony and documents in this case reveals that Arizant attempted to formulate a design for a distal filter to be added to the Bair Hugger, and even enlisted an outside design firm to create a solution, but eventually abandoned the project.

As emphasized above, a clearance under 510(k) is not an approval by the federal government that the product is safe in general or safe for any particular use. In addition, it appears that the information about the device which has been given to the FDA over the years has not been accurate or complete. Moreover, a significant body of scientific literature has identified an infection hazard from the use of the Bair Hugger, and Defendants chose to ignore this evidence.

Given all of the material I have reviewed, it is my opinion that Defendants' 510(k) clearance and subsequent regulatory interactions are not sufficient to ensure the safe use of the Bair Hugger 750 in orthopedic implant surgeries. It is also my opinion that Defendants failed to follow common practices in the medical device manufacturing industry by failing to adequately investigate the issue of the Bair Hugger's impact on orthopedic implant surgeries and adequately

[24] Leaper, Albrecht, Gauthier. *Forced air warming: a source of airborne contamination in the operating room?* Orthopedic Review, October 17, 2009.
[25] 3M00018949
[26] *Id.*

mitigate this hazard. The corporate memoranda and testimony I reviewed shows that the Defendants treated these issues as a marketing problem rather than a patient safety issue that merited serious scientific inquiry and safer resolution. Therefore, I conclude that the Defendants did not act as a reasonably prudent medical device manufacturer would act in response to these issues, and that the Defendants failed to meet their regulatory obligations to adequately ensure patient safety.



Yadin David
September 28, 2015

EXHIBIT 7

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

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PERIOPERATIVE NORMOTHERMIA TO REDUCE THE INCIDENCE OF SURGICAL-WOUND INFECTION AND SHORTEN HOSPITALIZATION

ANDREA KURZ, M.D., DANIEL I. SESSLER, M.D., AND RAINER LENHARDT, M.D.,
FOR THE STUDY OF WOUND INFECTION AND TEMPERATURE GROUP*

Abstract *Background.* Mild perioperative hypothermia, which is common during major surgery, may promote surgical-wound infection by triggering thermoregulatory vasoconstriction, which decreases subcutaneous oxygen tension. Reduced levels of oxygen in tissue impair oxidative killing by neutrophils and decrease the strength of the healing wound by reducing the deposition of collagen. Hypothermia also directly impairs immune function. We tested the hypothesis that hypothermia both increases susceptibility to surgical-wound infection and lengthens hospitalization.

Methods. Two hundred patients undergoing colorectal surgery were randomly assigned to routine intraoperative thermal care (the hypothermia group) or additional warming (the normothermia group). The patients' anesthetic care was standardized, and they were all given cefamandole and metronidazole. In a double-blind protocol, their wounds were evaluated daily until discharge from the hospital and in the clinic after two weeks; wounds containing culture-positive pus were considered infected. The patients' surgeons remained unaware of the patients' group assignments.

Results. The mean (±SD) final intraoperative core temperature was 34.7±0.6°C in the hypothermia group and 36.6±0.5°C in the normothermia group ($P<0.001$). Surgical-wound infections were found in 18 of 96 patients assigned to hypothermia (19 percent) but in only 6 of 104 patients assigned to normothermia (6 percent, $P=0.009$). The sutures were removed one day later in the patients assigned to hypothermia than in those assigned to normothermia ($P=0.002$), and the duration of hospitalization was prolonged by 2.6 days (approximately 20 percent) in the hypothermia group ($P=0.01$).

Conclusions. Hypothermia itself may delay healing and predispose patients to wound infections. Maintaining normothermia intraoperatively is likely to decrease the incidence of infectious complications in patients undergoing colorectal resection and to shorten their hospitalizations. (N Engl J Med 1996;334:1209-15.)

WOUND infections are common and serious complications of anesthesia and surgery. A wound infection can prolong hospitalization by 5 to 20 days and substantially increase medical costs.[1,2] In patients undergoing colon surgery, the risk of such an infection ranges from 3 to 22 percent, depending on such factors as the length of surgery and underlying medical problems.[3] Mild perioperative hypothermia (approximately 2°C below the normal core body temperature) is common in colon surgery.[4] It results from anesthetic-induced impairment of thermoregulation,[5,6] exposure to cold, and altered distribution of body heat.[7] Although it is rarely desired, intraoperative hypothermia is usual because few patients are actively warmed.[8]

Hypothermia may increase patients' susceptibility to perioperative wound infections by causing vasoconstriction and impaired immunity. The presence of sufficient intraoperative hypothermia triggers thermoregulatory vasoconstriction,[9] and postoperative vasoconstriction is universal in patients with hypothermia.[10] Vasoconstriction decreases the partial pressure of oxygen in tissues, which lowers resistance to infection in animals[11,12] and humans (unpublished data). There is decreased microbial killing, partly because the production of oxygen and nitroso free radicals is oxygen-dependent in the range of the partial pressures of oxygen in wounds.[13,14] Mild core hypothermia can also directly impair immune functions, such as the chemotaxis and phagocytosis of granulocytes, the motility of macrophages, and the production of antibody.[15,16] Mild hypothermia, by decreasing the availability of tissue oxygen, impairs oxidative killing by neutrophils. And mild hypothermia during anesthesia lowers resistance to inoculations with *Escherichia coli*[17] and *Staphylococcus aureus*[18] in guinea pigs.

Vasoconstriction-induced tissue hypoxia may decrease the strength of the healing wound independently of its ability to reduce resistance to infection. The formation

From the Thermoregulation Research Laboratory and the Department of Anesthesia, University of California, San Francisco (A.K., D.I.S.); and the Departments of Anesthesiology and General Intensive Care, University of Vienna, Vienna, Austria (A.K., D.I.S., R.L.). Address reprint requests to Dr. Sessler at the Department of Anesthesia, 374 Parnassus Ave., 3rd Fl., University of California, San Francisco, CA 94143-0648.

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*The study investigators are listed in the Appendix.

of scar requires the hydroxylation of abundant proline and lysine residues to form the cross-links between strands of collagen that give healing wounds their tensile strength.[19] The hydroxylases that catalyze this reaction are dependent on oxygen tension,[20] making collagen deposition proportional to the partial pressure of arterial oxygen in animals[21] and to oxygen tension in wound tissue in humans.[22]

Although safe and inexpensive methods of warming are available,[8] perioperative hypothermia remains common.[23] Accordingly, we tested the hypothesis that mild core hypothermia increases both the incidence of surgical-wound infection and the length of hospitalization in patients undergoing colorectal surgery.

Methods

With the approval of the institutional review board at each participating institution and written informed consent from the patients, we studied patients 18 to 80 years of age who underwent elective colorectal resection for cancer or inflammatory bowel disease. Patients scheduled for abdominal–peritoneal pull-through procedures were included, but not those scheduled for minor colon surgery (e.g., polypectomy or colostomy performed as the only procedure). The criteria for exclusion from the study were any use of corticosteroids or other immunosuppressive drugs (including cancer chemotherapy) during the four weeks before surgery; a recent history of fever, infection, or both; serious malnutrition (serum albumin, less than 3.3 g per deciliter, a white-cell count below 2500 cells per milliliter, or the loss of more than 20 percent of body weight); or bowel obstruction.

The number of patients required for this trial was estimated on the basis of a preliminary study in which 80 patients undergoing elective colon surgery were randomly assigned to hypothermia (mean [±SD] temperature, 34.4±0.4°C) or normothermia (involving warming with forced air and fluid to a mean temperature of 37±0.3°C). The number of wound infections (as defined by the presence of pus and a positive culture) was evaluated by an observer unaware of the patients' temperatures and group assignments. Nine infections occurred in the 38 patients assigned to hypothermia, but there were only four in the 42 patients assigned to normothermia ($P = 0.16$). Using the observed difference in the incidence of infection, we determined that an enrollment of 400 patients would provide a 90 percent chance of identifying a difference with an alpha value of 0.01. We therefore planned to study a maximum of 400 patients, with the results to be evaluated after 200 and 300 patients had been studied. The prospective criterion for ending the study early was a difference in the incidence of surgical-wound infection between the two groups with a P value of less than 0.01. To compensate for the two initial analyses, a P value of 0.03 would be required when the study of 400 patients was completed. The combined risk of a type I error was thus less than 5 percent.[24]

Study Protocol

The night before surgery, each patient underwent a standard mechanical bowel preparation with an electrolyte solution. Intraluminal antibiotics were not used, but treatment with cefamandole (2 g intravenously every eight hours) and metronidazole (500 mg intravenously every eight hours) was started during the induction of anesthesia; this treatment was maintained for about four days postoperatively. Anesthesia was induced with thiopental sodium (3 to 5 mg per kilogram of body weight), fentanyl (1 to 3 μg per kilogram), and vecuronium bromide (0.1 mg per kilogram). The administration of isoflurane (in 60 percent nitrous oxide) was titrated to maintain the mean arterial blood pressure within 20 percent of the preinduction values. Additional fentanyl was administered on the completion of surgery, to improve analgesia when the patient emerged from anesthesia.

The patients were hydrated aggressively during and after surgery, because hypovolemia decreases wound perfusion and increases the incidence of infection.[25,26] We administered 15 ml of crystalloid per kilogram per hour throughout surgery and replaced the volume of blood lost with either crystalloid in a 4:1 ratio or colloid in a 2:1 ratio. Fluids were administered intravenously at rates of 3.5 ml per kilogram per hour for the first 24 postoperative hours and 2 ml per kilogram per hour for the subsequent 24 hours. Leukocyte-depleted blood was administered as the attending surgeon considered appropriate.

At the time of the induction of anesthesia, each patient was randomly assigned to one of the following two temperature-management groups with computer-generated codes maintained in numbered, sealed, opaque envelopes: the normothermia group, in which the patients' core temperatures were maintained near 36.5°C, and the hypothermia group, in which the core temperature was allowed to decrease to approximately 34.5°C. In both groups, intravenous fluids were administered through a fluid warmer, but the warmer was activated only in the patients assigned to extra warming. Similarly, a forced-air cover (Augustine Medical, Eden Prairie, Minn.) was positioned over the upper body of every patient, but it was set to deliver air at the ambient temperature in the hypothermia group and at 40°C in the normothermia group. Cardboard shields and sterile drapes were positioned in such a way that the surgeons could not discern the temperature of the gas inflating the cover. Shields were also positioned over the switches governing the fluid heater and the forced-air warmer so that their settings were not apparent to the operating-room personnel. The temperatures were not controlled postoperatively, and the patients were not informed of their group assignments.

Supplemental oxygen was administered through nasal prongs at a rate of 6 liters per minute during the first three postoperative hours and was then gradually eliminated while oxygen saturation was maintained at more than 95 percent. To minimize the decrease in wound perfusion due to activation of the sympathetic nervous system, postoperative pain was treated with piritramide (an opioid), the administration of which was controlled by the patient.

The attending surgeons, who were unaware of the patients' group assignments and core temperatures, determined when to begin feeding them again after surgery, remove their sutures, and discharge them from the hospital. The timing of discharge was based on routine surgical considerations, including the return of bowel function, the control of any infections, and adequate healing of the incision.

Measurements

The patients' morphometric characteristics and smoking history were recorded. The preoperative laboratory evaluation included a complete blood count; determinations of the prothrombin time and partial-thromboplastin time; measurements of serum albumin, total protein, and creatinine; and liver-function tests. The risk of infection was scored with a standardized algorithm taken from the Study on the Efficacy of Nosocomial Infection Control (SENIC) of the Centers for Disease Control and Prevention; in this scoring system, one point each is assigned for the presence of three or more diagnoses, surgery lasting two hours or more, surgery at an abdominal site, and the presence of a contaminated or infected wound.[2] The scoring system was modified slightly from its original form by the use of the diagnoses made at admission, rather than discharge. The risk of infection was quantified further with the use of the National Nosocomial Infection Surveillance System (NNISS), a scoring system in which the patient's risk of infection was predicted on the basis of the type of surgery, the patient's physical-status rating on a scale developed by the American Society of Anesthesiologists, and the duration of surgery.[3]

Core temperatures were measured at the tympanic membrane (Mallinckrodt Anesthesiology Products, St. Louis), with values recorded preoperatively, at 10-minute intervals intraoperatively, and at 20-minute intervals for 6 hours during recovery. Arteriovenous-shunt flow was quantified by subtracting the skin temperature of the fingertip from that of the forearm, with values exceeding 0°C indicating thermoregulatory vasoconstriction.[27] End-tidal concentrations of isoflurane and carbon dioxide were recorded at 10-minute intervals during anesthesia. Measurements of arterial blood pressure and heart rate were recorded similarly during anesthesia and for six hours thereafter. Oxyhemoglobin saturation was measured by pulse oximetry.

Thermal comfort was evaluated at 20-minute intervals for 6 hours postoperatively with a 100-mm visual-analogue scale on which 0 mm denoted intense cold, 50 mm denoted thermal comfort, and 100 mm denoted intense warmth. The degree of surgical pain was evaluated similarly, except that 0 mm denoted no pain and 100 mm the most intense pain imaginable. Shivering was assessed qualitatively, on a scale on which 0 denoted no shivering; 1, mild or intermittent shivering; 2, moderate shivering; and 3, continuous, intense shivering. All

the qualitative assessments were made by observers unaware of the patients' group assignments and core temperatures.

The patients' surgical wounds were evaluated daily during hospitalization and again two weeks after surgery by a physician who was unaware of the group assignments. Wounds were suspected of being infected when pus could be expressed from the surgical incision or aspirated from a loculated mass inside the wound. Samples of pus were obtained and cultured for aerobic and anaerobic bacteria, and wounds were considered infected when the culture was positive for pathogenic bacteria. All the wound infections diagnosed within 15 days of surgery were included in the data analysis.

Wound healing and infections were also evaluated by the ASEPSIS system,[28] in which a score is calculated as the weighted sum of points assigned to the following factors: the duration of antibiotic administration, the drainage of pus during local anesthesia, the débridement of the wound during general anesthesia, the presence of a serous discharge, the presence of erythema, the presence of a purulent exudate, the separation of deep tissues, the isolation of bacteria from fluid discharged from the wound, and a duration of hospitalization exceeding 14 days. Scores exceeding 20 on this scale indicate wound infection. As an additional indicator of infection, preoperative differential white-cell counts were compared with counts obtained on postoperative days 1, 3, and 6.

Collagen deposition in the wound was evaluated in a subgroup of 30 patients in the normothermia group and 24 patients in the hypothermia group. A 10-cm expanded polytetrafluoroethylene tube (Impra, International Polymer Engineering, Tempe, Ariz.) was inserted subcutaneously several centimeters lateral to the incision at the completion of surgery. On the seventh postoperative day, the tube was removed and assayed for hydroxyproline, a measure of collagen deposition.[29] The ingrowth of collagen in such tubes is proportional to the tensile strength of the healing wound[29] and the subcutaneous oxygen tension.[22]

Statistical Analysis

Outcomes were evaluated on an intention-to-treat basis. The number of postoperative wound infections in each study group and the proportion of smokers among the infected patients were analyzed by Fisher's exact test. Scores for wound healing, the number of days of hospitalization, the extent of collagen deposition, postoperative core temperatures, and potential confounding factors were evaluated by unpaired, two-tailed t-tests. Factors that potentially contributed to infection were included in a univariate analysis. Those that correlated significantly with infection were then included in a multivariate logistic regression with backward elimination; a P value of less than 0.25 was required for a factor to be retained in the analysis.

All the results are presented as means ±SD. A P value of less than 0.01 was required to indicate a significant difference in our major outcomes (the incidence of infection and the duration of hospitalization); a P value of less than 0.005 was considered to indicate a significant difference in postoperative temperature (to compensate for multiple comparisons); for all other data, a P value of less than 0.05 was considered to indicate a statistically significant difference.

Results

Patients were enrolled in the study from July 1993 through March 1995; 155 were evaluated at the University of Vienna, 30 at the University of Graz, and 15 at Rudolfstiftung Hospital. According to the investigational protocol, the study was stopped after 200 patients were enrolled, because the incidence of surgical-wound infection in the two study groups differed with an alpha level of less than 0.01. One hundred four patients were assigned to the normothermia group, and 96 to the hypothermia group. An audit confirmed that the patients had been properly assigned to the groups and that the slight disparity in numbers was present in the original computer-generated randomization codes. All the patients allowed their wounds to be evaluated daily during hospitalization. Ninety-four percent returned for the two-week clinic visit after discharge; those who did not were evenly distributed between the study groups and mostly returned to visit the private offices of their attending surgeons. The wound status of these patients was determined by calling the physician. No previously unidentified wound infections were detected in the clinic for the first time.

Table 1 shows that the characteristics, diagnoses, types of surgical procedure, duration of surgery, hemodynamic values, and types of anesthesia of the patients in the two study groups were similar. Nor did smoking status, the results of preoperative laboratory tests, or preoperative laboratory values differ significantly between the groups. The patients assigned to hypothermia required more transfusions of allogeneic blood ($P=0.01$). Intraoperative vasoconstriction was observed in 74 percent of the patients assigned to hypothermia but in only

Table 1. Characteristics of the Patients in the Two Study Groups.*

Characteristic	Normothermia (N = 104)	Hypothermia (N = 96)	P Value
Male sex (no. of patients)	58	50	0.70
Weight (kg)	73±14	71±14	0.31
Height (cm)	170±9	169±9	0.43
Age (yr)	61±15	59±14	0.33
History of smoking (no. of patients)	33	29	0.94
Diagnosis (no. of patients)			
Inflammatory bowel disease	10	8	0.94
Cancer	94	88	
Duke's stage			1.0
A	29	30	
B	37	34	
C	26	21	
D	2	3	
Operative site			0.61
Colon	59	51	
Rectum	35	37	
Preoperative variables			
Core temperature (°C)	36.8±0.4	36.7±0.4	0.08
Hemoglobin (g/dl)	12.6±2.3	12.7±2.0	0.74
Intraoperative variables			
Fentanyl administered (mg)	0.7±0.3	0.6±0.5	0.09
End-tidal isoflurane (%)	0.6±0.1	0.6±0.2	1.0
Arterial blood pressure (mm Hg)	91±17	95±18	0.11
Heart rate (beats/min)	74±17	76±13	0.35
Crystalloid (liters)	3.3±1.5	3.2±0.9	0.57
Colloid (liters)	0.2±0.3	0.2±0.3	1.0
Red-cell transfusion (no. of patients)	23	34	0.054
Volume of blood transfused (units)	0.4±1.0	0.8±1.2	0.01
Urine output (liters)	0.6±0.4	0.7±0.4	0.08
Duration of surgery (hr)	3.1±1.0	3.1±0.9	1.0
Ambient temperature (°C)	21.9±1.2	22.1±0.9	0.19
Oxyhemoglobin saturation (%)	97.3±1.5	97.5±1.3	0.32
Final core temperature (°C)	36.6±0.5	34.7±0.6	<0.001
Postoperative variables			
Hemoglobin (g/dl)	11.7±1.9	11.6±1.4	0.67
Prophylactic antibiotics (days)	3.7±1.9	3.6±1.4	0.67
SENIC score (no. of patients)			0.98
1	3	3	
2	95	88	
3	6	5	
NNISS score (no. of patients)			0.6
0	32	31	
1	49	39	
2	23	26	
Infection rate predicted by NNISS (%)	8.9	8.8	—
Oxyhemoglobin saturation (%)	98±1	98±1	1.0
Piritramide (mg)†	20±13	22±12	0.26

*Plus–minus values are means ±SD. SENIC denotes Study on the Efficacy of Nosocomial Infection Control, and NNISS National Nosocomial Infection Surveillance System.

†The administration of this analgesic agent was controlled by the patient.

6 percent of those assigned to normothermia ($P<0.001$). Core temperatures at the end of surgery were significantly lower in the hypothermia group than in the normothermia group (34.7±0.6 vs. 36.6±0.5°C, $P<0.001$), and they remained significantly different for more than five hours postoperatively (Fig. 1).

Postoperative vasoconstriction was observed in 78 percent of the patients in the hypothermia group; the vasoconstriction continued throughout the six-hour recovery period. In contrast, vasoconstriction, usually short-lived, was observed in only 22 percent of the patients in the normothermia group ($P<0.001$). Shivering was observed in 59 percent of the hypothermia group, but in only a few patients in the normothermia group. Thermal comfort was significantly greater in the normothermia group than in the hypothermia group (score on the visual-analogue scale one hour after surgery, 73±14 vs. 35±17 mm). The difference in thermal comfort remained statistically significant for three hours. Pain scores and the amount of opioid administered were virtually identical in the two groups at every postoperative measurement; hemodynamic values were also similar.

The overall incidence of surgical-wound infection was 12 percent. Although the SENIC and NNISS scores for the risk of infection were similar in the two groups, there were only 6 surgical-wound infections in the normothermia group, as compared with 18 in the hypothermia group ($P=0.009$) (Table 2). Most positive cultures contained several different organisms; the major ones were *E. coli* (11 cultures), *S. aureus* (7), pseudomonas (4), enterobacter (3), and candida (3). Culture-negative pus was expressed from the wounds of two patients assigned to hypothermia and one patient assigned to normothermia. The ASEPSIS scores were higher in the hypothermia group than in the normothermia group (13±16 vs. 7±10, $P=0.002$) (Table 2); these scores exceeded 20 in 32 percent of the former but only 6 percent of the latter ($P<0.001$).

In a univariate analysis, tobacco use, group assignment, surgical site, NNISS score, SENIC score, need for transfusion, and age were all correlated with the risk of infection. In a multivariate backward-elimination analysis, tobacco use, group assignment, surgical site, NNISS score, and age remained risk factors for infection (Table 3).

Four patients in the normothermia group and seven in the hypothermia group required admission to the intensive care unit ($P=0.47$), mainly because of wound dehiscence, colon perforation, and peritonitis. Two patients in each group died during the month after surgery. The incidence of infection was similar at each study hospital, and no one surgeon was associated with a disproportionate number of infections.

Table 2 shows that significantly more collagen was deposited near the wound in the patients in the normothermia group than in the patients in the hypothermia group (328±135 vs. 254±114 μg per centimeter). The patients assigned to hypothermia were first able to tolerate solid food one day later than those assigned to normothermia ($P=0.006$); similarly, the sutures were removed one day later in the patients assigned to hypothermia ($P=0.002$). The duration of hospitalization was 12.1±4.4 days in the normothermia group and 14.7±6.5 days in the hypothermia group ($P=0.001$). This difference was statistically significant even when the analysis was limited to the uninfected patients. In the normothermia group, the duration of hospitalization was 11.8±4.1 days in patients without infection and 17.3±7.3 days in patients with infection ($P=0.003$). In the hypothermia group the duration of hospitalization was 13.5±4.5 days in patients without infection and 20.7±11.6 days in patients with infection ($P<0.001$).

The postoperative hemoglobin concentrations did not differ significantly between the two groups (Table 1). On the first postoperative day, leukocytosis was impaired in the hypothermia group as compared with the normothermia group (white-cell count, 11,500±3500 vs. 13,400±2500 cells per cubic millimeter; $P<0.001$). On the third postoperative day, however, white-cell counts were significantly higher in the hypothermia group (10,100±3900 vs. 8900±2900 cells per cubic millimeter). The difference in values on the third day was not statistically significant when only uninfected patients were included in the analysis. By the sixth postoperative day, the white-cell counts were similar in the two groups.

Among smokers, the number of cigarettes smoked per day was similar in the two groups (22±20 in the hy-

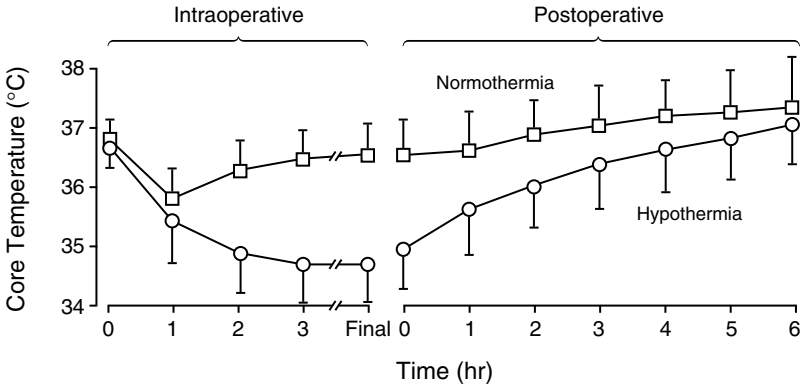

Figure 1. Core Temperatures during and after Colorectal Surgery in the Study Patients.

The mean (±SD) final intraoperative core temperature was 34.7±0.6°C in the 96 patients assigned to hypothermia, who received routine thermal care, and 36.6±0.5°C in the 104 patients assigned to normothermia, who were given extra warming. The core temperatures in the two groups differed significantly at each measurement, except before the induction of anesthesia (first measurement) and after six hours of recovery.

Table 2. Postoperative Findings in the Two Study Groups.*

Variable	Normothermia (N = 104)	Hypothermia (N = 96)	P Value
All patients			
Infection — no. of patients (%)	6 (6)	18 (19)	0.009
ASEPSIS score	7±10	13±16	0.002
Collagen deposition — μg/cm	328±135	254±114	0.04
Days to first solid food	5.6±2.5	6.5±2.0	0.006
Days to suture removal	9.8±2.9	10.9±1.9	0.002
Days of hospitalization	12.1±4.4	14.7±6.5	0.001
Uninfected patients			
No. of patients	98	78	
Days to first solid food	5.2±1.6	6.1±1.6	<0.001
Days to suture removal	9.6±2.6	10.6±1.6	0.003
Days of hospitalization	11.8±4.1	13.5±4.5	0.01

*Plus–minus values are means ±SD.

pothermia group vs. 22±14 in the normothermia group). The morphometric characteristics, anesthetic care, and SENIC and NNISS scores of smokers and nonsmokers were not significantly different. Nonetheless, the proportion of patients with wound infection was significantly higher among smokers (23 percent, or 14 of 62) than among nonsmokers (7 percent, or 10 of 138; P=0.004). Furthermore, the length of hospitalization was significantly greater among smokers (14.9±6.7 days, vs. 12.9±5.0 days among nonsmokers; P=0.02) (Table 4).

Discussion

The initial hours after bacterial contamination are a decisive period for the establishment of infection.[25] In surgical patients, perioperative factors can contribute to surgical-wound infections, but the infection itself is usually not manifest until days later.

In our study, forced-air warming combined with fluid warming maintained normothermia in the treated patients, whereas the unwarmed patients had core temperatures approximately 2°C below normal.[8] Perioperative hypothermia persisted for more than four hours and thus included the decisive period for establishing an infection.[25,30] The patients with mild perioperative hypothermia had three times as many culture-positive surgical-wound infections as the normothermic patients. Moreover, the ASEPSIS scores showed that in the patients assigned to hypothermia the reduction in resistance to infection was twice that in the normothermia group.

The types of bacteria cultured from our patients' surgical wounds were similar to those reported previously.[2,3] These organisms are susceptible to oxidative killing, which is consistent with our hypothesis that hypothermia inhibits the oxidative killing of bacteria.[31] The overall incidence of infection in our study was approximately 35 percent higher than in previous reports.[3] One explanation for this relatively high incidence is that we considered all wounds draining pus that yielded a positive culture to be infected, although some may have been of minor clinical importance. The hospitalizations of infected patients were one week longer than those of patients without surgical-wound infections, however, indicating that most infections were substantial. Similar prolongation of hospitalization has been reported previously.[1,2]

It is interesting to note that hospitalization was also prolonged (by about two days) in the uninfected patients in the hypothermia group (Table 2). A number of factors influenced the decision to discharge patients, but healing of the incision (formation of a "healing ridge," for example) was among the most important. As is consistent with a delay in clinical healing, sutures were removed significantly later and the deposition of collagen (an index of scar formation and the strength of the healing wound) was significantly less in the hypothermia group than in the normothermia group. That the patients assigned to hypothermia required significantly more time before they could tolerate solid food is also consistent with impaired healing.

In Austria's medical system, administrative factors and costs of hospitalization do not influence the length of stay in the hospital. No data on individual costs are tabulated by the participating hospitals, and they are therefore not available for our patients. Nonetheless, the cost of a prolonged hospitalization must exceed the cost of fluid and forced-air warming (approximately $30 in the United States). In a managed-care situation, the duration of hospitalization might have differed less, or not at all. However, our data suggest that patients kept at normal temperatures during surgery would be better prepared for discharge at a fixed time than those allowed to become hypothermic.

Among all 200 patients in our study, those who smoked had three times more surgical-wound infections and significantly longer hospitalizations than the nonsmokers. Similar data have been reported previously.[32] Numerous factors contributed to these results; one may have been that smoking markedly lowers oxygen tension in tissue for nearly an hour after each cigarette.[33] (Thermoregulatory vasoconstriction produces a similar reduction.[34]) The distribution of factors known to influence infection was similar between smokers and nonsmokers, but the smokers may have had other behavioral or physiologic factors predisposing them to infection.

The prevalence of smoking was similar in the two

Table 3. Multivariate Analysis of Risk Factors for Surgical-Wound Infection.

Risk Factor	Odds Ratio (95% Confidence Interval)
Tobacco use (yes vs. no)	10.5 (3.2–34.1)
Group assignment (hypothermia vs. normothermia)	4.9 (1.7–14.5)
Surgical site (rectum vs. colon)	2.7 (0.9–7.6)
NNISS score (per unit increase)*	2.5 (1.2–5.3)
Age (per decade)	1.6 (1.0–2.4)

*NNISS denotes National Nosocomial Infection Surveillance System.

Table 4. Postoperative Findings in the Study Patients According to Smoking Status.*

Variable	Smokers (N = 62)	Nonsmokers (N = 138)	P Value
Infection — no. of patients (%)	14 (23)	10 (7)	0.004
ASEPSIS score	15±18	8±10	<0.001
Days to suture removal	10.9±3.5	10.1±2.0	0.04
Days of hospitalization	14.9±6.7	12.9±5.0	0.02
SENIC score			0.25
1	0	6	
2	58	125	
3	4	7	
NNISS score			0.08
0	23	40	
1	30	58	
2	9	40	

*Plus–minus values are means ±SD. SENIC denotes Study on the Efficacy of Nosocomial Infection Control, and NNISS National Nosocomial Infection Surveillance System.

study groups. Other factors may have influenced the patients' susceptibility to wound infections, such as arterial hypoxemia, hypovolemia, the concentration of the anesthetic used, and vasoconstriction resulting from pain-induced stress.[25,26,35,36] However, the administration of oxygen, oxyhemoglobin saturation, fluid balance, hemodynamic responses, end-tidal concentrations of anesthetic, pain scores, and quantities of opioid administered were all similar between the two groups. These factors are therefore not likely to have confounded our results. It is also unlikely that exaggerated bacterial growth aggravated the infections in the hypothermia group, because small reductions in temperature actually decrease growth in vitro.[37]

Mild hypothermia can increase blood loss and the need for transfusion during surgery.[38] In vitro studies suggest that perioperative hypothermia may aggravate surgical bleeding by impairing the function of platelets and the activity of clotting factors.[39,40] Blood transfusions may increase susceptibility to surgical-wound infections by impairing immune function.[41] Our patients assigned to hypothermia required significantly more allogeneic blood to maintain postoperative hemoglobin concentrations than did the patients assigned to normothermia. However, we administered only leukocyte-depleted blood, and multivariate regression analysis indicated that a requirement for transfusion did not independently contribute to the incidence of wound infection. It is thus unlikely that the differences in the incidence of infection in the two groups we studied resulted from transfusion-mediated immunosuppression.

In summary, this double-blind, randomized study indicates that intraoperative core temperatures approximately 2°C below normal triple the incidence of wound infection and prolong hospitalization by about 20 percent. Maintaining intraoperative normothermia is thus likely to decrease infectious complications and shorten hospitalization in patients undergoing colorectal surgery.

We are indebted to Heinz Scheuenstahl for the collagen-deposition analysis; to Helene Ortmann, M.D., Andrea Hubacek, M.D., Michael Zimpfer, M.D., and Gerhard Pavecic for their generous assistance; and to Mallinckrodt Anesthesiology Products, Inc., for the donation of thermometers and thermocouples.

Appendix

The following investigators also participated in this study: **patient safety and data auditing:** H.W. Hopf and T.K. Hunt (University of California, San Francisco); **site directors:** G. Polak (Hospital Rudolfstiftung, Vienna, Austria) and W. Kröll (University of Graz, Graz, Austria); **patient care:** F. Lackner and R. Fuegger (University of Vienna); **data acquisition:** E. Narzt (University of Vienna), C. Wolrab (University of Vienna), E. Marker (University of Vienna), A. Bekar (Orthopedic Hospital, Speising, Vienna), H. Kaloud (University of Graz), U. Stratil (Hospital Rudolfstiftung), and R. Csepan (University of Vienna); **wound evaluation:** V. Goll (University of Vienna), G.S. Bayer (University of Vienna), and P. Steindorfer (University of Graz); and **data management:** B. Petschnigg (University of Vienna).

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EXHIBIT 8

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- -

DEPOSITION OF KARL D. ZGODA

VOLUME I, PAGES 1 - 238

FEBRUARY 24, 2017

(The following is the deposition of KARL D. ZGODA, taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, in the City of Minneapolis, State of Minnesota, commencing at approximately 9:08 o'clock a.m., February 24, 2017.)

APPEARANCES:

On Behalf of the Plaintiffs:

Mark D. Bankston
Kyle W. Farrar
William R. Ogden
KASTER, LYNCH, FARRAR & BALL, LLP
1010 Lamar
Suite 1600
Houston, Texas 77002

Noah Lauricella
GOLDENBERG LAW
800 LaSalle Avenue
Suite 2150
Minneapolis, Minnesota 55402

On Behalf of the Defendants:

Peter J. Goss
BLACKWELL BURKE P.A.
432 South Seventh Street
Suite 2500
Minneapolis, Minnesota 55415

On Behalf of the Deponent:

William A. Brewer III
Dale O. Fresch
BREWER ATTORNEYS & COUNSELORS
1717 Main Street
Suite 5900
Dallas, Texas 75201

ALSO PRESENT:

Jason L. Przymus, Videographer

EXAMINATION INDEX

EXHIBIT INDEX

A. Yes. It -- It came up initially as part of the Project Ducky. I'd never had discussions before of that.

Q. Okay. And I want to look here in this project, if you will go with me to page 23.

A. Okay.

Q. You're familiar with what IonArmour is; correct?

A. Yes.

Q. Okay. And there was a company, IonArmour, who could apply anti-macterial coatings to medical equipment; correct?

A. I'm not sure I'd characterize it as that. They were a company that had the technology to apply antimicrobial coatings to products, but they didn't really have the ability to -- to do it in production for companies. It was more of a, what I would call a technology or proof-of-concept idea at the time.

Q. Sure. And in fact if we look on this page, if we see that at the --

In the bottom there's a chart; correct?

A. Yes.

Q. See this cost chart that I'm looking at? And it says if the enhancement is done by Arizant in-house, that would -- you could do it on a

C E R T I F I C A T E

I, Debby J. Campeau, hereby certify that I am qualified as a verbatim shorthand reporter; that I took in stenographic shorthand the testimony of KARL D. ZGODA at the time and place aforesaid; and that the foregoing transcript consisting of 236 pages is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Lino Lakes, Minnesota, this 28th day of February, 2017.

DEBBY J. CAMPEAU

Notary Public

EXHIBIT 9

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

- - - - - - - - - - - - - - - - - -

In Re:

Bair Hugger Forced Air Warming

Products Liability Litigation

This Document Relates To:

All Actions MDL No. 15-2666 (JNE/FLM)

- - - - - - - - - - - - - - - - - -

DEPOSITION OF WINSTON T. TAN

VOLUME I, PAGES 1 - 117

MARCH 10, 2017

(The following is the deposition of WINSTON T. TAN, taken pursuant to Notice of Taking Deposition, via videotape, at the offices of Ciresi Conlin L.L.P., 225 South 6th Street, Suite 4600, Minneapolis, Minnesota, commencing at approximately 9:10 o'clock a.m., March 10, 2017.)

APPEARANCES:

On Behalf of the Plaintiffs:

Kyle W. Farrar
KASTER, LYNCH, FARRAR & BALL LLP
1010 Lamar, Suite 1600
Houston, Texas 77002

On Behalf of Defendants:

Peter J. Goss
BLACKWELL BURKE P.A.
432 South Seventh Street, Suite 2500
Minneapolis, Minnesota 55415

Dale O. Fresch
BREWER ATTORNEYS & COUNSELORS
1717 Main Street, Suite 5900
Dallas, Texas 75201

ALSO APPEARING:

Ryan M. Stirewalt, Videographer

I N D E X

competitive landscape.

Q. Okay. That one was specifically told to you, but in terms of why keeping the hose clean, you didn't have a specific reason as to why you were doing it, just doing it.

A. Other than there was competitors that had --

Q. Okay. And the --

You and your team come up with three concepts: an insertable filter, modular disposable hose, or self-cleaning system; correct?

A. And these were really-out-of-this-world type of exploratory.

Q. Okay. These are just -- yeah. These are ideas that smart guys in a room come up with; right?

A. Yeah. This was just white space.

Q. Right.

But these are ideas that are feasible; right? I mean you -- you could design -- design these types of systems; correct?

MR. GOSS: Object to form.

A. No, not all.

Q. Okay. Well let's talk about the --

I'm not going to go through this in -- in detail, but the insertable filter --

And you've got a handful of pages here of

11:45:54 you to change it?
11:46:00 A. "Change Filter," "Check Engine Light."
11:46:04 Possibly. I'm not a hundred percent
11:46:07 certain.
11:46:07 Q. Okay. Your refrigerator has a filter that
11:46:09 tells you when to change it. There's a light comes
11:46:12 on, something like this; right?
11:46:14 A. Not my particular refrigerator, but I know
11:46:16 what you mean.
11:46:16 Q. Okay. Is that kind of what this is
11:46:18 referring to, like a --
11:46:19 Because if you look at the drawing, there's
11:46:21 "Change Filter" and then like a little light that's
11:46:23 coming up.
11:46:23 A. Yes.
11:46:24 Q. A self-contained system would be a system
11:46:28 that takes the air that's blown on the patient and
11:46:31 puts it back into the system; correct?
11:46:33 A. So as I read -- mentioned earlier, not all
11:46:37 ideas are feasible, --
11:46:38 Q. Okay.
11:46:39 A. -- and so these back-end ones were just
11:46:42 like -- just ideas that's not technically feasible.
11:46:47 Q. So it's your testimony that in 2014 it was
11:46:51 not technically feasible to have a self-contained

11:46:54 system?
11:46:57 A. Yes.
11:46:59 Q. Why would you even discuss it if it -- if it
11:47:03 couldn't be made?
11:47:03 A. So when you do brainstorming, you don't
11:47:07 knock any ideas. You know, you bring all ideas, even
11:47:10 the ones that doesn't really make technical sense,
11:47:14 But --
11:47:15 It's just brainstorm. It's a brainstorming
11:47:18 exercise. That's all.
11:47:18 Q. If you go to page 16 --
11:47:23 And Mr. Tan, I know you weren't necessarily
11:47:25 involved with unidirectional flow and how the Bair
11:47:28 Hugger affects that, but a self-contained system would
11:47:32 eliminate any disruption in unidirectional flow;
11:47:35 correct?
11:47:36 MR. GOSS: Object to form, foundation, calls
11:47:38 for speculation.
11:47:39 A. I don't know.
11:47:39 Q. Well it doesn't have an exhaust; right?
11:47:42 A. I'm not familiar with that term, so I'm not
11:47:44 sure.
11:47:44 Q. You're not familiar with the term "exhaust?"
11:47:46 A. No, the "unidirectional flow."
11:47:48 Q. Fair enough.

C E R T I F I C A T E

I, Richard G. Stirewalt, hereby certify that I am qualified as a verbatim shorthand reporter, that I took in stenographic shorthand the deposition of WINSTON T. TAN at the time and place aforesaid, and that the foregoing transcript is a true and correct, full and complete transcription of said shorthand notes, to the best of my ability.

Dated at Deerwood, Minnesota, this 12th day of March, 2017.

RICHARD G. STIREWALT
Registered Professional Reporter
Notary Public

EXHIBIT 10

TO DECLARATION OF M. JOSEPH WINEBRENNER IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' EXPERT DR. YADIN DAVID

HEPA Filters Do Not Affect Infection Rates following Primary Total Joint Arthroplasty with Forced Air Warmers

Curtis GL, Faour M, Klika AK, Barsoum WK, Higuera CA

Background: Forced-air warmers (FAW) have been used effectively to prevent hypothermia, but some studies have suggested that FAW may increase bacterial contamination of the surgical site. To address this, a new generation of FAW with high efficiency particulate air filters (FAW-HEPA) were introduced. This study compared infection rates following total joint arthroplasty (TJA) procedures using FAW and FAW-HEPA.

Methods: Patients who underwent primary TJA at a large academic center and two high-volume arthroplasty regional hospitals within a single healthcare system were retrospectively reviewed. In 2014, the hospital system switched from FAW (3M, St. Paul, MN) to FAW-HEPA (Stryker, Kalamazoo, MI). A total of 5,405 TJA cases in 2013 and 2015 were identified. Patients in 2013 (n=2,792) had procedures with FAW, while patients in 2015 (n=2,613) had procedures with FAW-HEPA. The primary measured outcome was the incidence of infection within 90 days of surgery. Prosthetic joint infection (PJI) was defined as reoperation with arthrotomy or meeting MSIS criteria for PJI. Surgical site infection (SSI) was defined as a wound complication treated with antibiotics or irrigation and debridement. The χ^2-test was used for univariate analysis, while logistic regression models were adjusted for age, gender, comorbidities, BMI, and operative time.

Results: The groups had no differences in demographics or comorbidities, but operative time was significantly longer in the FAW-HEPA group (111 min vs 108 min; Table 1, p=0.001). The FAW group had a higher rate of SSI (n=33 [1.18%] vs. n=22 [0.84%]; Table 2, p=0.21), but a lower rate of PJI than the FAW-HEPA group (n= 13 [0.47%] vs. n=20 [0.77%]; Table 2, p=0.15). The regression model did not show FAW to be an independent risk factor for infection. FAW did not significantly increase the risk of SSI (Table 3, OR=1.47; 95% CI0.83 –2.58; p=0.18), PJI (OR=0.53; 95% CI 0.25–1.13; p=0.09), or total infection (Table 3, OR=1.00; 95% CI 0.65–1.57; p=0.97).

Discussion: No statistically significant differences in SSI and PJI were found between FAW and FAW-HEPA use during TJA. Although studies have suggested that FAW increase infection risk, this study found no clinical difference.

Conclusions: FAW devices are not correlated to a higher risk of infection during TJA when compared to devices with HEPA filters.

Table 1. Comparison of patient demographics

Demographics TJA (n = 5,405)	FAW[a] n = 2,792	FAW-HEPA[b] n = 2,613	p-value
Age, Mean ± SD	63.2 ± 11.1	62.8 ± 11.3	0.19
Gender, Male (%)	1,224 (43.8)	1,206 (46.2)	0.08
Charlson Comorbidity Index, Mean ± SD	3.72 ± 1.99	3.70 ± 2.04	0.76
Body Mass Index, Mean ± SD	31.8 ± 6.8	32.0 ± 7.1	0.22
Operative Time, minutes, Mean ± SD	108 ± 37	111 ± 37	0.001

[a]Forced-air warmer
[b]Forced-air warmer with high efficiency particulate air filter

Table 2. Univariate analysis

Outcomes (%) TJA (n = 5,405)	FAW[a] n = 2,792	FAW-HEPA[b] n = 2,613	p-value
Surgical Site Infection (%)	33 (1.18)	22 (0.84)	0.21
Periprosthetic Joint Infection (%)	13 (0.47)	20 (0.77)	0.15
Total infection (%)	46 (1.65)	42 (1.61)	0.90

[a]Forced-air warmer
[b]Forced-air warmer with high efficiency particulate air filter

Table 3. Multivariate analysis

Total Joint Arthroplasty	Odds Ratio (95% Confidence Interval)	p-value
Surgical Site Infection	1.47 (0.83 – 2.58)	0.18
Periprosthetic Joint Infection	0.53 (0.25 – 1.13)	0.09
Total infection	1.00 (0.65 – 1.57)	0.97

FAW-HEPA used as reference
Factors adjusted for in the logistic regression model: Age, Gender, Charlson Index Score, Body Mass Index, and Operative Time.